**Clinical Interventional Research Agreement for PI’s**

Between

**Epworth Foundation
(trading as Epworth HealthCare)**

and

[Insert Principal Investigator’s Name]

This Agreement is made between Epworth and a PI with an appointment at Epworth conducting clinical interventional research activities or clinical trials at/or for Epworth HealthCare.

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**This Agreement** is made on the day of 20\_\_\_.

## Parties

**Epworth Foundation** (ABN 97 420 694 950)of 89 Bridge Road, Richmond, VIC 3121 (**Epworth**).

and

**[insert name]** of **[insert address**], in the State of **[insert**] (**Principal Investigator**).

## Recitals

A The Principal Investigator holds a current appointment with Epworth pursuant to the Epworth By-Laws 2015.

B The Principal Investigator is or intends to conduct a Study at Epworth and Epworth will enter into a CTRA as the Responsible Institution for the conduct of the Study and the Principal Investigator acknowledges that any Study is within their scope of practice.

C Epworth wishes to facilitate the conduct of the Study by the Principal Investigator at Epworth and agrees to make its facilities and staff available for that purpose.

D The Principal Investigator agrees to conduct the Study in accordance with the CTRA, the Protocol, any requirements of the Sponsor, and on terms and conditions set out in this Agreement.

## Operative Provisions

**The parties now agree as follows**:

#### Term

* 1. This Agreement commences on **[insert date]** and continues until the earlier of the following:
		1. the date that the last of Study is completed at Epworth and final clinical research data is provided by the Principal Investigator or Epworth to the Sponsor; or
		2. the date this Agreement is terminated in accordance with **clause 6.3** or by mutual agreement of the Parties.

#### Responsibilities

* 1. The Institution and the Principal Investigator will perform the Study in a professional and competent manner and, in order of precedence, in accordance with:
		1. all applicable Commonwealth and State laws;
		2. all relevant requirements of the Therapeutic Goods Administration;
		3. the GCP Guidelines;
		4. the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 2004;
		5. the National Statement on Ethical Conduct in Research Involving Humans 2007 (updated 2018) as produced by the National Health and Medical Research Council of Australia;
		6. the Protocol for the Study; and
		7. any condition of the approving Human Research Ethics Committee.

**Epworth**

* 1. Epworth will:
		1. make available adequate facilities, equipment and other resources at Epworth, as reasonable required to safely follow the Protocol for use by the Principal Investigator and Study Subjects;
		2. provide all co-operation and assistance to the Principal Investigator and Sponsor necessary or convenient for the effective and efficient conduct of the Study;
		3. have adequate security measures to ensure the safety and integrity of the Study Drug, Essential Documents and Study records and reports, Equipment and any Study related materials held or located at the Study Site; and
		4. permit access to the Essential Documents and Study records and reports and other Study related materials as soon as is reasonably possible upon request by the Sponsor, Human Research Ethics Committee or any third party designated by the Sponsor.

**Principal Investigator**

* 1. The Principal Investigator is authorised by Epworth as the person responsible for the day to day conduct and direction of the Study. The Principal Investigator does not have any authority from Epworth to amend the Protocol.
	2. The Principal Investigator must:
		1. thoroughly familiarises himself or herself with the appropriate use of the Study Drug, as described in the Protocol, Investigator’s Brochure, information relating to the Study Drug and any other information sources provided by the Sponsor;
		2. provide the Sponsor with evidence of his/her 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;
		3. be 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; and
		4. advise Epworth as soon as practicable of any intention to leave the Institution or otherwise cease to be involved in the conduct of the Study at Epworth and where practicable use reasonable endeavours to nominate a replacement acceptable to Epworth and the Sponsor.
	3. The Principal Investigator warrants that he or she 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.

**Human Research Ethics Committee approval**

* 1. Prior to commencing the Study, the Principal Investigator must obtain written authorisation from a certified Human Research Ethics Committee.
	2. The Principal Investigator must notify the Human Research Ethics Committee of any changes to the Protocol or any other changes to the Study which are required to be notified to it.

**Informed Consent**

* 1. The Principal Investigator must ensure that written consent has been obtained from each patient participating in the Study, prior to the Study Subject commencing participation in the Study. Such consent must be documented by the Study Subject’s dated signature on the agreed Participant Information and Consent Form or otherwise in accordance with law. The signed Participant Information and Consent Form must be kept on the Study Subject’s file.

**Information to Staff**

* 1. The Principal Investigator must:
		1. provide all personnel involved in the Study with the information reasonably required for the conduct of the Study, and
		2. ensure that all such persons sign such confidentiality undertakings and assignments of intellectual property which are requested by the Sponsor.

**Data**

* 1. The Principal Investigator, or an Authorised Delegate, must collect and report data promptly and properly, and keep Epworth and the Sponsor regularly informed of the status of the Study, especially with regard to the recruitment of patients.
	2. The Principal Investigator, or an Authorised Delegate, must complete the case report forms provided by the Sponsor accurately and completely and maintain those forms and any records and data documentation required by the Protocol. The Principal Investigator, or an Authorised Delegate, must use their best endeavours to do so within the observation period specified in the Protocol.
	3. The Principal Investigator, and the Authorised Delegate, agree to make all forms, records, documentation, data and other information arising from or relating to the Study available to Epworth and the Sponsor and to any relevant government regulatory authority for audit purposes, in accordance with the Protocol. Where it is necessary to do so in order to preserve any Study Subject confidentiality or privacy rights which have not been waived in the Sponsor’s favour under the relevant patient consent form. The Principal Investigator and the Authorised Delegate must provide the subject matter referred to in this clause to the Sponsor, edited only to preserve the anonymity of the Study Subject.

**Data Retention**

* 1. The Principal Investigator must retain all information relating to Study Subjects and other data relating to the Study for at least 15 years in the case of adults and at least 23 years in the case of children following completion or discontinuation of the Study, or as otherwise required by law.

**Reporting**

* 1. The Principal Investigator must, within 24 hours of their occurrence, notify Epworth and the Sponsor of the following:
		1. withdrawal of Human Research Ethics Committee approval;
		2. any deviation from the Protocol; or
		3. any audit or inquiry regarding the Study by any government authority.
	2. The Principal Investigator must comply with the safety reporting plan approved by the Human Research Ethics Committee in accordance with the NHMRC guidance and TGA annotations on the GCP.
	3. The Principal Investigator must ensure that the Authorised Delegate complies with the obligations attributed to him/her in this Agreement.

**Study Drug**

* 1. The Principal Investigator must:
		1. ensure that all Study Drug 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 Study Drug; and
		3. keep all Study Drug 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 Study Drug.

#### Changes to the Protocol

3.1 Any changes to the Protocol must be made with the prior agreement of the Sponsor, the Principal Investigator, Epworth and be approved by the Human Research Ethics Committee.

3.2 If generally accepted standards of clinical practice relating to the safety of Study Subjects require a deviation from the Protocol, such standards must be followed. If a party becomes aware of the need for a deviation from the Protocol it must immediately notify the other party of the facts causing the deviation as soon as the facts are known to that party.

#### Intellectual Property

4.1 The Principal Investigator acknowledges that all Intellectual Property relating to the Study shall be the property of and owned by the Sponsor. Epworth and the Principal Investigator may use any Intellectual Property in accordance with the terms of the CTRA.

4.2 The Principal Investigator agrees to disclose promptly to the Sponsor or its nominees full particulars of any Intellectual Property that the Principal Investigator makes, discovers or conceives during the course of the Study that relates to the Study Drug or Study Materials.

4.3 The Principal Investigator agrees to assign, and will ensure that their staff and contractors assign, all such interests to the Sponsor or its nominee.

#### Duty to preserve confidentiality and privacy

5.1 A party must not disclose any of another party’s Confidential Information, unless one or more of the following applies, the disclosure:

* + 1. is necessary in connection with performing obligations under this Agreement or under another Agreement between the parties;
		2. is to an officer, employee, agent or consultant of the party, to the extent that he or she needs to know Confidential Information in order to perform a function in connection with this Agreement;
		3. is required by law;
		4. is reasonably made to a professional legal adviser or professional auditor;
		5. is reasonably required as part of a party’s internal complaint accident reporting, quality assurance or disciplinary procedures;
		6. is for thepurpose of notifying Study Subjects, Principal Investigators, medical practitioners administering treatment to Study Subjects**,** Human Research Ethics Committees and Regulatory Authorities of any material risks identified during the Study or subsequent to it;
		7. is required to comply with the requirements of any regulatory authority;
		8. is for the purpose of the monitoring of the Study by the Human Research Ethics Committee;
		9. is to an agreed insurer; or
		10. relates to Confidential Information and the party consents in writing to the disclosure.

5.2 To remove doubt, as between the parties, in respect of Study Subject information, Epworth and the Principal Investigator owe confidentiality obligations to both the Study Subject and to the Sponsor.

**Privacy**

5.3 The Principal Investigator agrees to comply with all Victorian privacy, health records or similar legislation which the Principal Investigator and Institution are required to comply with, including, but not limited to the *Health Services Act* 1988 (Vic) and the *Health Records Act* 2001 (Vic) and *Privacy Act* 1998 (Cth).

5.4 The Principal Investigator must promptly report to the Institution and the Sponsor any unauthorised access to or use or disclosure of personal information of the Study Participants.

**Continuing obligations**

5.5Clauses 4 and 5 continue to apply despite the termination or ending of this Agreement.

**Publication**

5.6 The Principal Investigator and any Authorised Delegate acknowledge their right to publish the methods, results of, and conclusions from the Study subject to the terms of clause 11 of the CTRA.

#### Indemnity and insurance

## Principal Investigator aware of risks

6.1 The Principal Investigator is aware of the potential risks associated with the conduct of the Study.

**Liability and indemnity**

6.2 Subject to the terms of any indemnity provided by the Sponsor in favour of the Principal Investigator and Epworth, the Principal Investigator is liable for and continually indemnifies Epworth and its officers, employees, representatives and agents against all loss suffered or incurred by any of those indemnified as a result of a breach of this Agreement. Without limiting the above, this includes any loss caused by:

 6.2.1 a breach of the obligations of confidentiality and privacy;

 6.2.2 any negligent or wrongful acts or intentional misconduct by the Principal Investigator or its employees, agents or subcontractors; or

 6.2.3 personal injury (including death) which is caused by a failure of the Principal Investigator or its employees, agents or subcontractors to conduct the Study strictly in accordance with the Protocol.

**Insurance**

* 1. The Principal Investigator must maintain during the term of this Agreement professional indemnity insurance for an amount not less than $10 million in respect of any one claim, and for a period of 7 years after the completion of the Study.

The Principal Investigator must notify its insurer of its involvement in the Study.

#### Termination

**Termination by notice**

7.1 A party may terminate this Agreement by giving 30 days’ written notice to the other parties.

**Termination of Agreement due to breach**

7.2 Subject to the exercise of any rights by Epworth or the Sponsor under the CTRA, a party may terminate this Agreement immediately, by giving notice in writing to the other parties, if:

* + 1. one of the other parties commits a breach of this Agreement which is not rectifiable and that party after receiving a written notice from a party, does not pay the reasonable compensation required by that party to make good the breach; or
		2. one of the other parties fails to rectify a breach of this Agreement which is rectifiable within 30 days after receiving a written notice from a party specifying the breach and requiring the other party to rectify it;
		3. one of the parties 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
		4. one of the parties assigns this Agreement without the other parties’ consent.

**Immediate termination**

* 1. A party may terminate this Agreement immediately if:
		1. approval to conduct the Study is withdrawn by the relevant regulatory or health authorities or by the Human Research Ethics Committee;
		2. continuing the Study poses an unacceptable risk to the rights, interests, safety or well-being of Study Participants;
		3. after mutual consultation, the parties agree in writing that it is inappropriate, impractical or inadvisable to continue the Study; or
		4. the CTRA is terminated by the Sponsor.

#### Dispute

8.1 No party may commence legal proceedings against another in respect of a dispute 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”).

* 1. If the dispute is not resolved within the Initial Period, then the dispute shall be referred within a further 28 days of 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 Institute of Victoria. Any documents produced for the mediation are to be kept confidential and cannot be used except for the purpose of settling the dispute.
	2. 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.
	3. 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.

#### Miscellaneous

**Approvals and consent**

* 1. Except as otherwise set out in this Agreement, a party may give or withhold an approval or consent to be given under this Agreement in that party’s absolute discretion and subject to any conditions determined by the party. A party is not obliged to give its reasons for giving or withholding a consent or for giving a consent subject to conditions.

**No agency or partnership**

* 1. The relationship between the Sponsor on the one hand and the Principal Investigator and Institution on the other is that of principal and independent contractor. The Sponsor and Institution are not the agent or partner of the other by virtue of this Agreement.

**Assignment**

* 1. A party must not assign any of its rights or obligations under this Agreement without the prior written consent of the other parties.

**Costs**

* 1. Each party is responsible for its own costs incurred in relation to preparing, negotiating and executing this Agreement and any document related to this Agreement.

**Further acts**

* 1. Each party must promptly execute all documents and do all things that another party from time to time reasonably requests to effect, perfect or complete this Agreement and all transactions incidental to it.

**Governing law and jurisdiction**

* 1. This Agreement is governed by the law of Victoria. The parties submit to the non-exclusive jurisdiction of its courts and courts of appeal from them. The parties will not object to the exercise of jurisdiction by those courts on any basis.

**Severability**

* 1. If a clause or part of a clause of this Agreement can be read in a way that makes it illegal, unenforceable or invalid, but can also be read in a way that makes it legal, enforceable and valid, it must be read in the latter way. If any clause or part of a clause is illegal, unenforceable or invalid, that clause or part is to be treated as removed from this Agreement, but the rest of this Agreement is not affected.

**Variation**

* 1. No variation of this Agreement will be of any force or effect unless it is in writing and signed by the parties to this Agreement.

**Waiver**

* 1. The fact that a party fails to do, or delays in doing, something the party is entitled to do under this Agreement, does not amount to a waiver of any obligation of, or breach of obligation by, another party. A waiver by a party is only effective if it is in writing. A written waiver by a party is only effective in relation to the particular obligation or breach in respect of which it is given. It is not to be taken as an implied waiver of any other obligation or breach or as an implied waiver of that obligation or breach in relation to any other occasion.

#### Definitions and interpretation

* 1. In this Agreement the following definitions apply:

**Adverse Event** has the meaning given in the TGA document “Australian Clinical Trial Handbook” (2018) or its replacement;

**Authorised Delegate** means a person named as a sub-investigator in the Study and any other persons agreed in writing by the parties from time to time;

**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.

**Confidential Information** means information (wherever it was obtained) in relation to a party’s:

(a) business, operations or strategies;

(b) intellectual or other property;

(c) actual or prospective patients;

(d) 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; or

* + 1. the Protocol, information relating to the Protocol, Study Materials and Study Drug.

The information must be any one of the following:

(a) confidential in fact;

(b) reasonably regarded by the party a confidential;

(c)information that a written notice from the party to the other party states is confidential.

Information is not confidential if:

(a) it is in the public domain, unless it came into the public domain by a breach of confidentiality;

(b) it is already known by the other party not under any obligation of confidentiality at the time this Agreement is entered into; or

(c) it is obtained lawfully from a third party without any breach of confidentiality.

**CTRA** means a Clinical Trial Research Agreement, Medicines Australia – Standard form entered into for a 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, and as amended from time to time.

**Human Research Ethics Committee** means the Human Research Ethics Committee reviewing a Study on behalf of Epworth.

**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 as recognised by the law in force in the State or Territory where Epworth is located; and
			2. any application or right to apply for registration of any of those rights.

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

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

**Protocol** means the protocol for a Study which is a designated number and all subsequent revisions.

**Responsible Institution** means the Institution named as such in the CTRA and for the purpose of this Agreement is Epworth.

**Serious Adverse Event** has the meaning given in the TGA document “Australian Clinical Trial Handbook (2018)” or its replacement, and for the avoidance of doubt includes Suspected unexpected serious adverse reactions (SUSARs), Unanticipated serious adverse device effects (USADEs), and Significant Safety Issues (SSIs);

**Sponsor** means the Sponsor of the Study as set out in the CTRA.

**Study** means a clinical research study or studies initiated by a Sponsor and made known to Epworth including all subsequent revisions of the Study.

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

**Study Drug** means the drug the subject of the Study as referred to in the Protocol.

**Study Materials** means all the materials and information, including all data, results, case report forms, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed or as a result of the Study.

**Study Site** means the location(s) under the control of Epworth where the Study is located.

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

**TGA** means the Therapeutic Goods Administration of the Commonwealth of Australia.

**Interpretation**

* 1. In the interpretation of this Agreement, the following provisions apply unless the context otherwise requires:
		1. A reference to a Business Day means a day other than a Saturday or Sunday on which banks are open generally in Melbourne, Victoria;
		2. If the day which any act, matter or thing is to be done under this Agreement is not a Business Day, the act, matter or thing must be done on the next Business Day;
		3. A reference in this Agreement to dollars or $ means Australian dollars and all amounts payable under this Agreement are payable in Australian dollars;
		4. A reference in this Agreement to any law, legislation or legislative provision includes any statutory modification, amendment or re-enactment, and any subordinate legislation or regulations issued under that legislation or legislative provision;
		5. A reference in this Agreement to any Agreement or document is to that Agreement or document as amended, novated, supplemented or replaced;
		6. A reference to a clause or schedule is a reference to a clause or schedule of this Agreement;
		7. Where a word or a phrase is given a defined meaning, another part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning;
		8. A word which denotes the singular denotes the plural, a word which denotes the plural denotes the singular, and a reference to any gender denotes the other genders; and
		9. References to the word “include” or “including” are to be construed without limitation.

## Execution and date

Executed as an Agreement

Date: ……/……/……..

**Signed** by ……………………………………………

**[insert name]**

for and on behalf of the **Epworth Foundation**,

(ABN 97 420 694 950)

*Signature of witness*

……………………………………………

(*name printed in full*)

……………………………………………

……………………………………………

(*address*)

……………………………………………

……………………………………………

**Signed** by ……………………………………………

**[insert name of Principal Investigator]**

Date: ……/……/…..…

in the presence of:

*Signature of witness*

……………………………………………

(*name printed in full*)

……………………………………………

……………………………………………

(*address*)

……………………………………………

……………………………………………