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**C****linical Trial Research Agreement**

**EpiNet Study Group Collaborative Research – Standard Form**

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| The body of this Agreement (that is from the following page to the execution clauses) is intended to be identical to the standard form copy available at <http://www.epinet.co.nz/index.cfm?PageID=2> Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 3 by way of Special Conditions. |

**Details of the parties**

|  |  |
| --- | --- |
| **Name of Institution:** |  |
| Address: |  |
| Contact for Notices: |  |
| Fax for Notices: |  |
| Phone Number: |  |

|  |  |
| --- | --- |
| **Name of CRG:** | **EpiNet Study Group**  |
| Address: | c/o Neurology DepartmentAuckland City HospitalAuckland, New Zealand |
| Contact for Notices: | Dr Peter Bergin |
| Fax for Notices: | +6493078912 |
| Phone Number: | +6493074949 \* 25663 |

|  |  |  |
| --- | --- | --- |
| **Study Name:** | EpiNet First Trials 1 - 5 |  |
| Protocol Number: | **2.0** |  |
| Date of Agreement: | Date of last signature |  |

**This agreement is made between the EpiNet Study Group and the Institution**

**Purpose of the Agreement**

According to this Agreement:

1. The EpiNet Study Group is an academic, non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating research into epilepsy using the EpiNet database and is represented by the EpiNet Steering Committee.
2. The Institution, through the Principal Investigator, is responsible for the conduct of the Study at the Study Site(s).
3. The Study will be conducted on the terms and conditions set out below.
4. The parties acknowledge that the Study will be conducted in the spirit of cooperation and collaboration and not for the benefit of any pharmaceutical company.

**OPERATIVE PROVISIONS**

# INTERPRETATION

## In this Agreement:

**Adverse Event** has the meaning given in the *Clinical Safety and Data Management: Definitions and Standards for Expedited Reporting (ICH Harmonised Tripartite Guideline E2A) and the study protocol.*

**Affiliate** means any entity which (directly or indirectly) controls, is controlled by or is under common control with the EpiNet Study Group.

**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

**Case Report Form** means an electronic document, database or form, provided through the EpiNet Database site, designed to record all of the information, which is required by the Protocol to be reported to the EpiNet Study Group on each Study Participant.

**Confidential Information** means:

### in respect of the EpiNet Study Group:

#### 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;

#### the Protocol, the Investigator’s Brochure, information related to the Protocol, Study Materials and Investigational Product;

#### know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques owned by the EpiNet Study Group or its Affiliates;

#### know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study; and

#### information concerning the business affairs of the EpiNet Study Group or its Affiliates;

### 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.

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

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

**EpiNet Study Group** means the group which comprises all the investigators involved in the EpiNet Project as listed on the EpiNet website and represented by the EpiNet Steering Committee.

**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), and for New Zealand sites, as adopted with annotation by Medsafe, or its replacement.

**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:

### 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

### any application for 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.

**Personal Information** means information about an identifiable individual

**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** [**2**](#Text21) 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 Responsible EC.

**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 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 Institution and any overseas regulatory authorities who may audit or require to be audited, any part of the Study or Study Materials.

**Responsible EC** means the Ethics Committee responsible for reviewing the Study on behalf of the Institution as described in **Schedule 1**.

**Relevant Privacy Laws** means any legislation, code or guideline which applies in the jurisdiction in which the Institution is located and which relates to the protection of personal or health information.

**Serious Adverse Event** has the meaning given in the *Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (ICH Harmonised Tripartite Guideline E2A)* and study protocol.

### **Software** means the software supplied to the Institution by or on behalf of the EpiNet Study Group for the purposes of the Study, including that specified in **Schedule 1** and in particular, the EpiNet Database.

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

**Study Completion** means:

### (1) the Case Report Forms for the Study have been locked; or

### (2) all study follow-up requirements have been met, and a copy of the letter from Responsible EC acknowledging receipt of the final report and/or closure letter from the Principal Investigator has been received by the EpiNet Study Group; or

### (3) as otherwise determined by the EpiNet Study Group 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 EpiNet Study Group including all data, results, 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) where the Study is actually conducted as set out in **Schedule 1**.

## Except where the context otherwise requires:

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

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

### any reference to a person or body includes a partnership and a body corporate or body politic;

### words in the singular include the plural and vice versa;

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

### 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;

### 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;

### references to a party includes its Personnel.

# THE STUDY

## The parties must comply with, and conduct the Study in accordance with the Protocol and any conditions of the Responsible EC. In addition the parties must comply with the following, as applicable:

### any requirements imposed by law or of Regulatory Authorities;

### the requirements of any publication or guideline that relates or may relate to clinical trials, or regulations governing the conduct of clinical research in the jurisdiction of the Study;

### the GCP Guideline;

### the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996;

### any Study specific and standard operating procedures provided by the EpiNet Study Group prior to the commencement of the Study; and

### any reasonable direction given by the EpiNet Study Group in order to ensure the safe conduct of the Study and compliance with applicable regulatory requirements.

## 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 EpiNet Study Group and the Responsible EC 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.

## From time to time, the EpiNet Study Group 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 Responsible EC.

# PRINCIPAL INVESTIGATOR

## **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.

## **Liability for Principal Investigator**

For the purpose of this Agreement only, and as between the EpiNet Study Group 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.

## **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:

### 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 EpiNet Study Group;

### ensures written approval has been obtained to conduct the Study from the Responsible EC and the Institution prior to Study initiation. Written documentation of approval by the Responsible EC and the Institution must be provided to the EpiNet Study Group;

### 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 EpiNet Study Group and the Institution and approved in accordance with **clause 3.3(4)**;

### ensures that any amendments to the Protocol are approved by the Responsible EC and EpiNet Study Group prior to implementation of the amendment in accordance with **2.3**;

### as soon as is practical advises the EpiNet Study Group if the Responsible EC alters its approval of the Study;

### obtains prior written approval from the EpiNet Study Group and the Responsible EC of any proposed advertisements to be used for the purpose of Study Participant recruitment in the Study (as applicable);

### provides the EpiNet Study Group 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;

### uses his or her best endeavours to recruit eligible Study Participants, within the recruitment period, , provided that if the overall target number of Study Participants, specified in **Schedule 1,** for the Study is reached, the EpiNet Study Group may direct the Institution to cease recruitment;

### is available when a clinical research representative of the EpiNet Study Group 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;

### notifies the EpiNet Study Group, the Institution and the Responsible EC of any 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 EC with their policies and procedures;

### completes Case Report Forms in the EpiNet database within the agreed time period.

### provides regular written progress reports to the EpiNet Study Group in relation to the Study as required by the Protocol;

### completes and returns to the EpiNet Study Group as required any Study related materials within a reasonable time period;

### 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;

### 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 EpiNet Study Group, the Institution and the Responsible EC.

## Despite any other remedy provided in this Agreement, where an Investigator is in breach of any of these obligations the EpiNet Study Group may, on written notice, take any or all of the following actions:

1. Suspend the Investigator’s ability to recruit new Study Participants;
2. Suspend the Investigator’s ability to participate in the Study;
3. De-accredit the Study Site.

# INSTITUTION OBLIGATIONS AND RESPONSIBILITIES

## If the Principal Investigator leaves the Institution or otherwise ceases to be available then:

### the institution must notify the EpiNet Study Group as soon as is practical;

### the Institution must consult with the EpiNet Study Group and use reasonable endeavours to nominate as soon as practicable a replacement reasonably acceptable to both parties; and

### if a replacement cannot be found who is acceptable to both parties, the EpiNet Study Group may require recruitment into the Study by the Institution to cease, and the EpiNet Study Group may terminate this Agreement in accordance with **clause 13.4**.

## If the Principal Investigator fails to carry out those obligations specified in **clauses 3.3(1),** **(2), (4),** **(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.

## The Institution warrants that to the best of its knowledge, it, 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 for debarment. Furthermore, the Institution shall notify the EpiNet Study Group as soon as practical after it becomes aware of any such disqualification, disbarment or ban.

## The Institution will not engage in any conduct on the EpiNet Study Group’s behalf which is in violation of, or potentially in violation of, any applicable local or foreign laws or regulations.

## The Institution warrants, represents and undertakes to the EpiNet Study Group 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 EpiNet Study Group (**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.

## The Institution must have adequate security measures to ensure the safety and integrity of the Essential Documents and Study records and reports and any Study related materials held or located at the Study Site.

## Subject to **clause 8**, the Institution will allow monitoring as required by the EpiNet Steering Committee, 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 EpiNet Study Group, Regulatory Authority, Responsible EC or any third party designated by the EpiNet Study Group. 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.

## 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 EC.

## 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 Participants will attend an investigator meeting or a pre-study/initiation meeting, where appropriate.

## 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 EpiNet Study Group. The Institution agrees to notify the EpiNet Study Group before destroying any Study Materials.

## The Institution will ensure that the Study is subject to the continuing oversight of the Responsible EC throughout its conduct.

## If the Institution is contacted by any Regulatory Authority in connection with the conduct of the Study, the Institution shall immediately notify the EpiNet Study Group, unless prevented from doing so by law.

## The Institution will provide the EpiNet Study Group 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 EpiNet Study Group in connection with the requirements of a Regulatory Authority or the EpiNet Study Group as a result of such an audit.

## The Institution shall obtain approval, in writing, from the EpiNet Study Group 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:

### law;

### any policy, guideline or direction of government or any government department or agency;

### any Regulatory Authority; or

### 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.

# EpiNet Study Group OBLIGATIONS AND RESPONSIBILITIES

## Prior to the Agreement being executed, the EpiNet Study Group or its designate must provide the Principal Investigator, and through the Principal Investigator the Institution and the Responsible EC, with all current and relevant information regarding the Investigational Product that is reasonably available to the EpiNet Study Group and required to justify the nature, scope and duration of the Study.

## The EpiNet Study Group 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 2.1**.

## The EpiNet Study Group will register the Study on the appropriate clinical trials registry.

## The EpiNet Study Group will designate appropriately qualified personnel to advise on Study-related medical questions or problems.

## The EpiNet Study Group will, as soon as it becomes aware, advise the Institution, through the Principal Investigator of the cessation elsewhere of any relevant trial, or the withdrawal of an Investigational Product from any other market for safety reasons.

## The EpiNet Study Group will notify the Institution of any 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.

## The EpiNet Study Group will cooperate with the Institution and/or the Responsible EC in investigating any Serious Adverse Event arising out of or in connection with the Study.

## To assist the Institution to comply with **clause 7**, the EpiNet Study Group will provide the Institution with adequate information and all necessary product accountability forms.

## The Institution acknowledges that the EpiNet Study Group has no obligation to make any payments to the Institution in consideration of the Institution conducting the Study.

# PROVISION OF SOFTWARE

## The EpiNet Study Group will make the software available to the Institution and Principal Investigator at no cost to the Institution.

## The Institution agrees that the Principal Investigator and Institution’s Personnel will make themselves familiar with the Software and any training document provided by the EpiNet Study Group for this purpose.

## Subject to **clause 6.6**, at any time after Study Completion, the Institution must comply with any request from the EpiNet Study Group to return all related training materials and documentation provided by the EpiNet Study Group to the EpiNet Study Group.

## The EpiNet Study Group grants the Institution a non-exclusive licence to use the EpiNet Database. The EpiNet Study Group retains the right to discontinue the EpiNet Database at its discretion. Where the EpiNet Study Group intends to discontinue the EpiNet Database it will give 30 days prior notice to permit the transfer of records as required.

## The EpiNet Study Group will comply with any reasonable request from the Institution to assist in maintaining the Software in good working order, and ensuring that it is compliant with the requirements of the relevant licensing and safety authorities at all times.

## The Institution will not copy the Software unless specifically authorised by the EpiNet Study Group.

# INVESTIGATIONAL PRODUCT & PRODUCT LIABILITY

## The Institution acknowledges that all Investigational Products are registered in the Institution’s country and are available as standard treatments. The EpiNet Study Group will not provide any Investigational Product to the Institution.

## The Institution will be responsible for obtaining the allocated Investigational Product. The Institution is responsible for funding the cost of treatment and may charge the participant provided:

### the cost of treatment would be funded by the participant if they were not part of the study; and

### the costs are explained to the participant prior to giving consent to participation and randomisation.

# CONFIDENTIALITY

## Subject to **clause 8.2**, 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 it rights or the performance of its obligations under this Agreement.

## The Institution may use or disclose EpiNet Study Group Confidential Information in any of the following circumstances:

### 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;

### 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**,** Responsible ECs and Regulatory Authorities;

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

### to enable the Responsible EC to monitor the Study;

### where the EpiNet Study Group consents in writing to the disclosure;

### as part of a publication issued under the provisions of **clause 12**;

### where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the EpiNet Study Group, and subject to the Institution upon request providing reasonable assistance to enable the EpiNet Study Group to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure

### for the purposes of obtaining legal advice; and

### disclosure to the Institution’s insurer.

## Where Confidential Information is disclosed in accordance with **clause 8.2(1)**, **8.2(4) or 8.2(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.

## The EpiNet Study Group may disclose Institution Confidential Information on a needs to know and confidential basis to its Affiliates and for the purpose of obtaining legal advice. The EpiNet Study Group may disclose Institution Confidential Information if required by law, with notice as soon as reasonably practical to the Institution, and subject to the EpiNet Study Group 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.

## The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in this **clause 8**, 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.

## Information will not be Confidential Information and subject to the provisions of this **clause 8** where:

### the information has been independently received from a third party who is free to disclose it;

### the information is in or has entered the public domain other than as a result of a breach of this Agreement;

### the party already knew the information, the prior knowledge of which it can document by prior written records; or

### the party independently develops, discovers or arrives at the information without use, reference to, or reliance upon, the Confidential Information.

# PRIVACY

## 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.

## 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.

# LIABILITY AND INSURANCE

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

## The Institution 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.

# PUBLICATIONS

## 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 EpiNet Steering Committee, 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 EpiNet Study Group.

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

## 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:

### 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.

### 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.

# STUDY RESULTS AND INTELLECTUAL PROPERTY

## The EpiNet Study Group grants to the Institution and its Personnel the right to use the Background IP of the EpiNet Study Group 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 EpiNet Study Group

## 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 Intellectual Property remains the sole property of the Institution. The Institution grants to the EpiNet Study Group 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 for the commercialisation of the Study Materials.

## Subject to **clause 12.2**, all Intellectual Property in the Study Materials will vest automatically upon its creation in the EpiNet Study Group, and the Institution presently assigns the EpiNet Study Group 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 EpiNet Study Group’s expense.

## As a general principle, any Intellectual Property specifically relating to any Investigational Product shall be the sole property of the company owning the Investigational Product. Nothing in this Agreement transfers any Intellectual Property rights (other than a right to use where expressly stated in this Agreement) in the Investigational Product to the Institution or the Principal Investigator.

## The Institution must promptly disclose and communicate in writing to the EpiNet Study Group 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.

# TERM AND TERMINATION

## 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 EpiNet Study Group or Institution. In the ordinary course of events this Agreement terminates on Study Completion.

## 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:

### 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;

### 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

### assigns this Agreement to a person considered unsuitable to perform the Agreement as set out in **clause 19.3**.

## 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:

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

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

## The EpiNet Study Group 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(3)**.

## The EpiNet Study Group may terminate this Agreement with 30 days prior written notice to the Institution.

## 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 EpiNet Study Group (or destroy if requested by the EpiNet Study Group, and provide evidence of such destruction) any completed Case Report Forms and other materials received from the EpiNet Study Group before Study Completion.

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

## In the event of early termination, the EpiNet Study Group will cooperate with the Institution to ensure that Study Participants who may be affected by termination receive adequate medical care.

## The following provisions survive termination of this Agreement, **clauses 1.1**, **1.2**, **4.7,** **4.10**, **8,** **9, 10, 11, 12, 13, 14, 15, 16, 17, 18** and **19.**

# DISPUTES

## 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**”).

## If the dispute is not resolved within the Initial Period then the parties are free to pursue any procedures available at law for the resolution of the dispute, including mediation if the parties agree it is appropriate.

## 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.

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

# APPLICABLE LAW

This Agreement will be governed by, and construed in accordance with, the laws of New Zealand and the courts of New Zealand shall have non-exclusive jurisdiction in any proceedings relating to it.

# NOTICES

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

### delivered to the party’s address; or

### sent by pre-paid mail to the party’s address; or

### transmitted by facsimile to the party’s address; or

### sent by email to the party’s email address.

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

### if delivered to a person’s address, on the day of delivery if a business day, otherwise on the next business day; or

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

### 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; or

### if sent by email to the address specified on page 1 and a delivery receipt confirming delivery to that address is received by the sender, on the date of delivery specified in the delivery receipt if a business day, otherwise on the next business day.

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

17.4 Any notice delivered, sent or transmitted after 5pm in the place of receipt will be deemed to have been delivered at 9am on the following business day.

# WAIVER

## 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.

## 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.

# VARIATIONS

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

# ASSIGNMENT

## 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**).

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

### the name and the address of the proposed assignee or novatee;

### a copy of the proposed deed of assignment or novation; and

### such other information as the Other Party reasonably requires.

## Provided the proposed novatee is a New Zealand entity, the Other Party must give its consent promptly if:

### the Assigning Party satisfies 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;

### 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;

### the Assigning Party is not in breach of this Agreement; and

### 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**.

# ENTIRE AGREEMENT

This Agreement together with its schedules 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.

# 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.

# 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.

# 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.

# 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.

# COUNTERPARTS

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

# 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 **EpiNet Study Group**

|  |  |
| --- | --- |
| Signed: |  |
| Name: |  |
| Position:  |  |
| Date: |  / /  |

Signed on behalf of the **INSTITUTION**

|  |  |
| --- | --- |
| Signed: |  |
| Name:  |  |
| Position:  |  |
| Date: |  / /  |

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

Acknowledged by the **PRINCIPAL INVESTIGATOR**

|  |  |
| --- | --- |
| Signed: |  |
| Name:  |  |
| Position:  |  |
| Date: |  / /  |

1. : Key Information

*(to be inserted by EpiNet Study Group)*

|  |  |
| --- | --- |
| Study Name: | EpiNet First Trials 1 - 5 |
| Study Site/s: |  |
| Protocol Number: | **Protocol version 2 dated 17/06/2014** |
| Target number of Study Participants: | Minimum: **Not specified**Maximum: **Not specified** |
| Recruitment Period: | Start: April 15, 2015 |
| End: When 4500 patients across all sites and 5 EpiNet First Trials have been recruited |
| Principal InvestigatorName: |  |
| Address: |  |
|  |  |
|  |  |
|  |
| Responsible EC: |  |
| Software provided by the EpiNet Study Group | Access to EpiNet Database |
|  |  |
|  |  |
| Investigational Product(s): | Levetiracetam; Lamotrigine; Carbamazepine; Sodium Valproate |
|  |  |

1.
2. : Study Protocol Identification

|  |  |
| --- | --- |
| Full Title: | EpiNet-First Trials. A series of five pragmatic randomised controlled trials comparing the effectiveness of levetiracetam versus lamotrigine, carbamazepine and sodium valproate for untreated epilepsy: the EpiNet-First trials |
|  |  |
|  |  |
| Version Number: | 2.0 |
| Date: |  **17 / 06 / 2014**  |
| List of Key attachments: | EpiNet-First Protocol |
|  |  |
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1. : Special Conditions

**[Parties may insert special conditions by agreement as required to proceed with the study in the Institution’s jurisdiction or specific to the Institution’s requirements]**