**Clinical Trial Research Agreement for Investigator Initiated Teletrial**

The body of the Agreement is not to be amended. Revisions are to be detailed in Schedule 4 with appropriate cross-referencing to the relevant clause(s) in the Agreement.

**DETAILS OF THE PARTIES**

|  |  |
| --- | --- |
| **INSTITUTION ACTING AS SPONSOR (‘Institution’)****Name:****Address:****ABN:****Contact for Notices:** | Click or tap here to enter text.**Name**: **Position**: **Email**: **Telephone**:  |
| **OTHER INSTITUTION ACTING THROUGH SATELLITE SITE(S) (‘Other Institution’)****Name:****Address:****ABN:****Contact for Notices:** | **Name**: **Position**: **Email**: **Telephone**:  |
| **STUDY NAME:****PROTOCOL NUMBER:****DATE OF AGREEMENT:** |  |

**THIS AGREEMENT IS MADE BETWEEN THE INSTITUTION (acting as Sponsor) AND THE OTHER INSTITUTION (acting through the Satellite Site(s))**

**PURPOSE OF THE AGREEMENT**

A The Institution has prepared and owns the Protocol and may also agree to support the Study in other ways, for example, by providing funding for the Study or facilitating the supply of Investigational Product.

B The Institution wishes to conduct the Study as an Investigator initiated Teletrial.

**OPERATIVE PROVISIONS**

## **INTERPRETATION**

## In this Agreement:

**Activities** means the delegated activities described in **Item 14** of **Schedule** 1.

**Adverse Event** has the meaning given in the TGA document *Access to unapproved therapeutic goods – Clinical trials in Australia* (October 2004) or its replacement, published on the Australian Government Department of Health and Aged Care, TGA website.

**Agreement** means this Agreement, including all the Schedules hereto.

**Associate Investigator** has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.16).

**Background Intellectual Property or** **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 party 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.

**Business Day** means any day that is not a Saturday, Sunday or public holiday in the jurisdiction where a party is located.

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

**Certificate of Insurance** means the certificate of insurance required pursuant to **clause 12**.

**Confidential Information** means:

### in respect of the Institution:

#### 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 relating to the Protocol and Study Materials;

#### information, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Institution;

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

#### information concerning the business affairs or clients of the Institution; and

#### information in relation to the Institution’s business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors.

### in respect of the Other 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 as defined for the purposes of this Agreement.

## **Date of Agreement** means the date that this Agreement commences and is specified on the first page of this Agreement, or if such date is not included, the date that this Agreement is last signed by either the Institution or the Other Institution.

**Delegation Log** has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.12).

### **Equipment** means the equipment supplied to the Other Institution by or on behalf of the Institution 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 legal entity, acting as the Sponsor, 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 trademarks, 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** 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** means an investigator involved in the Study and includes the Principal Investigator and Associate Investigator.

**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.

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

**Other Institution** means the other party that is a legal entity and includes Satellite Sites that do not have a separate legal existence from the Other Institution.

**Personal Information** includes information that is defined as ‘personal information’, ‘health information’, ‘confidential information’ or a similar term for information identifying an individual as defined in Relevant Privacy Laws that apply to a party.

**Personnel** means officers, employees, sub-contractors, agents, authorised representatives, and includes in the case of the Institution, the Principal Investigator.

**Primary Site** has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.18).

**Principal Investigator** is the Investigator responsible for the conduct, management, monitoring and reporting of a trial at their own site, and assumes overall responsibility and provides oversight to Satellite Site(s) within a cluster and has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.16).

**Protocol** means the document identified in **Schedule 1** and has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.18).

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

**Publication** has a corresponding meaning.

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

**Relevant Privacy Laws** includes the *Privacy Act 1988* (Cth), *Privacy and Data Protection Act 2014* (Vic), legislation that regulates information that is defined as ‘confidential information’ and any other legislation, code or guideline, which applies to a party in the jurisdiction in which the Study Site is located, and 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**.

**Satellite Site** includes a health facility or health service, which is part of the Other Institution, and also meets the criteria for the definition of a satellite site in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.19).

### **Software** means the software supplied by the Institution for the purposes of the Study, including that specified in **Schedule 1**.

**Special Conditions** means the special conditions in **Schedule 4** of this Agreement.

**Sponsor** means the Institution acting as Sponsor which is the legal entity described on the first page of this Agreement.

**Study** means the clinical trial to be conducted in accordance with the Protocol, as described in Item 3 of **Schedule 2**.

**Study Completion** means the database for the Study has been locked and all Essential Documents have been provided to the Institution, 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 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) where the Study is actually conducted under the Protocol, including Satellite Sites participating in a Teletrial Cluster, as set out in **Schedule 1**.

**Supervision Plan** has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.21).

**Teletrial** has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.21).

**Teletrial Cluster** has the same meaning as in the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia*, published on the Australian Government Department of Health and Aged Care website (p.71).

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

## 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;

### the Special Conditions (if any) and all other provisions in any schedule to this Agreement are incorporated in, and form part of, this Agreement and bind the parties;

### 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;

### a reference to a monetary amount means that amount in Australian currency;

### a reference to a party means each party to this Agreement, its Personnel and persons for which it is vicariously liable, and its respective successors and permitted assigns; and

### references to a party includes its Personnel.

### If there is any inconsistency between the clauses of this Agreement and its Schedules, the order of priority in Item 6 of Schedule 2 will apply, with documents earlier in the list prevailing to the extent of the inconsistency.

## **STUDY**

## **Protocol**

### The Study is initiated by the Institution which also owns the Protocol. The Institution will act as Sponsor of the Study for the purposes of the TGA’s Clinical Trial Notification (CTN) Scheme (or any successor scheme).

1. The Institution is responsible for preparing and submitting all documents required by the TGA to file an application for initiating and conducting the Study.

## **Obligations and responsibilities of the Institution acting as the Sponsor**

### The Institution and all Satellite Sites participating in a Teletrial conducted through the Institution must comply with, and conduct the Study:

#### in accordance with the Protocol and any condition of the Reviewing HREC;

#### any requirements of relevant Commonwealth or State or Territory laws or of Regulatory Authorities;

#### the requirements of the TGA in document titled ‘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 Studies, or other such regulations or guidance governing the conduct of clinical research in the jurisdiction of the Study;

#### the GCP Guideline; and

#### the NHMRC National Statement on Ethical Conduct in Human Research (2007) or replacement, and any other relevant NHMRC publication or guideline that relates to clinical trials or Studies, including the documents comprising the National Teletrials Compendium.

### If any issue relating to the safety of Study Participants arises which requires a deviation from the Protocol, the Principal Investigator at the Primary Site or Associate Investigator at a Satellite Site 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 ensure that the Principal Investigator is aware of the Principal Investigator’s obligation to notify the Institution as 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 five (5) Business Days after the change is implemented.

## **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.

### Where the Study is being conducted as a Teletrial, the Principal Investigator at the Primary Site is responsible for the conduct of the Study across the Teletrial Cluster.

### **Liability for Principal Investigator**

### For the purpose of this Agreement 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.

### **The Institution is responsible for ensuring that the Principal Investigator:**

### 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 relevant information;

### ensures written approval has been obtained to conduct the Study from the Reviewing HREC, the Institution and the Other Institution prior to Study initiation;

### conducts the Study according to the Protocol without changes, except as provided in **clause 2.2**;

### ensures that any amendments to the Protocol are approved by the Reviewing HREC prior to implementation of the amendment;

### 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 the Reviewing HREC; and

### where the Study is being conducted as a Teletrial, agrees to provide oversight for the conduct of the Study across all Study Sites within the Teletrial Cluster and accepts responsibility for the same.

### If the Principal Investigator leaves the Institution or otherwise ceases to be available then the Institution must use reasonable endeavours to nominate a replacement, as soon as practicable.

## **SATELLITE SITE ACTIVITIES**

* 1. The Other Institution (acting through the Satellite Site) will perform the Activities in accordance with:

### the Protocol;

### the terms of this Agreement which apply to those Activities;

### the principles of good scientific and clinical research practices;

### all applicable local, State and Commonwealth laws, legislation, regulations, rules and by-laws;

### the TGA approval for the Study, the HREC Approval and all relevant Reviewing HREC directions issued from time to time; and

### the Supervision Plan and Delegation Log responsibilities agreed between the Primary Site and the Satellite Site.

* 1. The Other Institution warrants that each person engaged by it to perform any part of the Activities at the Satellite Site:

### is competent;

### has the necessary and appropriate qualifications, licences, admissions, memberships and skills to ensure they are both qualified and able to perform the relevant Activities; and

### in the case of any part of the Activities required to be performed by a health professional of a type subject to the Health Practitioner Regulation National Law as enacted in the jurisdiction in which the Activities will be performed, will be performed by a relevant health professional who meets their registration and accreditation requirements under that Act.

* 1. The Other Institution must not engage any allied health, nursing or medical Personnel to perform any part of the Activities, unless those Personnel are appropriately credentialed, including with the Institution, where required.
	2. The Other Institution must give written notice to the Institution as soon as possible, upon becoming aware that it no longer complies with the warranties and assurances provided in this clause.
	3. The Other Institution represents and warrants that:

### it has 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;

### it has documented information security policies, standards and/or procedures in place to protect the confidentiality, privacy and integrity of information in its possession and control, including Personal Information under Relevant Privacy Laws applying to the party; and

### it has reasonable measures in place for identifying threats and vulnerabilities to its information system(s), including in respect of Personnel training and mobile device storage.

## **PAYMENTS AND INVOICING**

* 1. The terms and conditions under this Agreement for the payment and invoicing between the parties of any fees in relation to the Study are specified in **Schedule 3**.
	2. The making of any payment is conditional on the provision of a valid tax invoice in accordance with GST Law.

## **INVESTIGATIONAL PRODUCT**

Where the Other Institution’s pharmacy will handle and dispense medicine(s) constituting an Investigational Product, it will:

### use the medicine(s) solely for the Study and not for any other purpose;

### abide by the same obligations and responsibilities as the Institution’s pharmacy; and

### dispose of, or destroy, the medicine(s) in accordance with the instructions of the Institution communicated by the Institution, and in accordance with applicable laws, regulations and the Institution’s policies and procedures.

## **PROVISION OF EQUIPMENT**

## 7.1 The Institution may provide the Other Institution with the Equipment; this will be at no charge. Unless otherwise agreed by the parties in writing, the Equipment will be used only by the Associate Investigator and Personnel involved in the conduct of the Study and only for the purposes of the Study.

## 7.2 The Other Institution will ensure the Equipment will be used in accordance with the Equipment's manufacturer's specifications and instructions.

## 7.3 All parties will take reasonable care in the use and secure storage of the Equipment.

## 7.4 The parties will cooperate in maintaining the Equipment in good working order and ensuring that it is in a safe condition and compliant with the requirements of the relevant licensing and safety authorities so long as it continues to be used for the purposes of the Study. The Institution will cover any out-of-pocket expenses in doing so.

## 7.5 When this Agreement ends, if requested by the Institution, the Other Institution must return the Equipment to the Institution or dispose it in an appropriate manner. If the Institution makes no such request within seven (7) days after the Agreement ends, the Other Institution will be deemed to be the owner of the Equipment and may use it in any manner it wishes.

## **MEETINGS**

The Other Institution’s Associate Investigator for the Study will meet with the Principal Investigator, and as agreed, other Investigators for the Study in relation to the Study as convened by, and agreed with, the Institution from time to time, including to discuss findings, the conduct of the Activities and any amendment or variation to the Protocol that may be required from time to time.

## **MONITORING VISITS AND REGULATORY AUTHORITIES**

* 1. Subject to **clause 11**, the Other Institution will allow regular monitoring visits.
	2. If the Other Institution is contacted by any Regulatory Authority in connection with the conduct of the Study it will immediately notify the Institution, unless prevented from doing so by law.
	3. The Other Institution will provide the Institution 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 Institution 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 Institution unless such rectification is due to the default of the Other Institution or its Personnel.
	4. The Other Institution:

### warrants that its Investigators and other Personnel involved in the Study are not and have not been debarred or disqualified from participating in clinical research by any Regulatory Authority, and that it will not employ, engage or communicate with any person or organisation in connection with the Study that is or has been so debarred or disqualified; and

### will promptly notify the Institution in the event that it becomes aware that it has used or involved, or is currently using or involving, in connection with the Study a person of the type described in this clause.

1. STUDY MATERIALS AND INTELLECTUAL PROPERTY

## The Institution will own the Study Materials.

* 1. Subject to complying with applicable laws including Relevant Privacy Laws, the Other Institution must:

### retain and preserve a copy of all Study Materials, as agreed with the Institution;

### ensure that no Study Materials are destroyed without the prior written approval of the Institution; and

### liaise with the Institution prior to destroying any Study Materials and retain the Study Materials for such longer period as reasonably required by the Institution.

## A party’s Background IP will remain vested solely in that party and nothing in this Agreement will be deemed to give the other party any rights to use or commercialise the same except as expressly provided in this Agreement.

## Each party grants to the other party a non-exclusive, non-transferable, royalty-free licence to use its Background IP to the extent necessary to conduct the Study.

* 1. All Intellectual Property in the Study Materials created by the Other Institution will vest automatically upon its creation in the Institution. The Other Institution agrees to execute or procure the execution by its Personnel of any documents reasonably necessary to give effect to this assignment, at the Institution’s expense.
	2. The Other Institution must promptly disclose and communicate in writing to the Institution full particulars of any Intellectual Property that the Other Institution or its Personnel make, discover or conceive in the course of the Study that is directly related to the Study Materials.
1. CONFIDENTIALITY and PRIVACY

## Subject to complying with Relevant Privacy Laws and **clause 11.2**, the parties must not, and must ensure their Personnel do not, use or disclose any Confidential Information, other than where and only to the extent such use or disclosure is necessary for the performance of the Study, the exercise of its rights or the performance of its obligations under this Agreement.

## Subject to compliance with Relevant Privacy Laws, the parties may use or disclose 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, Investigators, medical practitioners administering treatment to Study Participants, Reviewing HRECs and Regulatory Authorities;

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

### for the purposes of the monitoring of the Study by the Reviewing HREC;

### where the disclosing party consents in writing to the disclosure by the receiving party;

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

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

### where release of the Confidential Information is required by law;

### for the purposes of legal advice; and

### disclosure to a party’s insurer.

## Where Confidential Information is disclosed in accordance with **clauses 11.2(a), 11.2(d), 11.2(i) or 11.2(j)**, the Confidential Information must only be used in connection with the legitimate purposes of the party, and only disclosed to those who have a need to know it for such purposes and are obligated to keep the information confidential.

## The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in this **clause 11**, and are bound in similar terms to keep such information confidential.

## The parties must ensure that any Personal Information arising from the Study regarding Study Participants or Personnel, is collected, stored, used and disclosed 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.

1. INSURANCE
	1. The Other Institution warrants that it has, or will:

### effect and maintain professional indemnity and public liability insurance; and

### on request by the Institution, provide a Certificate of Insurance.

* 1. This **clause 12** continues in operation for so long as any obligations remain in connection with this Agreement.
	2. The Other Institution satisfies the requirements of **clause 12.1** if it is entitled to indemnity under a program or scheme of insurance or indemnity that is arranged by a State or Territory of the Commonwealth of Australia.
1. LIABILITY
	1. Each party is liable for its own acts and omissions in relation to the conduct of the Study.
	2. The parties acknowledge that they may agree to additional clauses in relation to indemnities and limitation, or limitation of liability as set out in the Special Conditions in Schedule 4, and in the event of inconsistency between this clause 13 and the Special Conditions, the Special Conditions will prevail.
2. PUBLICATIONS

## The Institution, Principal Investigator and other Investigators (‘**Discloser**’) involved in the Study have the right to Publish the methods, results of, and conclusions from, the Study, subject to this clause and in accordance with copyright law.

## All parties must ensure that the Discloser gives written notice of any proposed Publication drafted by them and/or other Personnel involved in the conduct of the Study to the Institution at least 40 calendar days before any forwarding to a party that is not bound by the confidentiality obligations set out in **clause 11**.

## The Institution may, within that 40-day period do any one or more of the following:

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

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

### request that the Discloser remove specified Confidential Information or Personal Information (other than the de-identified results of the Study) from the Publication, in which case such specified Confidential Information and/or Personal Information must be removed as is reasonably required to protect the Intellectual Property of the Institution and its obligations to comply with Relevant Privacy Laws.

## If the Discloser has not received any comments from the Institution on the proposed Publication within 40 calendar days of giving written notice to Institution under **clause 14.2**, the Discloser may proceed to make the Publication.

1. 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 party.

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

## Either party may terminate this Agreement with 30 calendar 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 calendar days of a written notice from the terminating party specifying the breach and requiring its remedy; or

### 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.

## In addition to **clause 15.3**, 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 Institution may terminate this Agreement with 30 calendar days prior written notice to the Other Institution. In the event of such early termination, the Institution will pay the reasonable costs of the Other Institution relating to the Study calculated in accordance with **Schedule 3**.

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

## In the event of early termination, the Institution will 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 Institution’s expense.

1. ANTI-BRIBERY / ANTI-CORRUPTION
	1. The Other Institution warrants, represents and undertakes 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 Other Institution, or the Institution (‘**Improper Payment**’), and has not received an Improper Payment, and will not offer, promise, pay, authorise or receive any Improper Payment in the future.
	2. For the purposes of this **clause 16**, 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.
2. 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 party 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 calendar days of the giving of that written notice (‘**Initial Period**’).

## If the dispute is not resolved within the Initial Period, then the dispute will be referred within a further 28 calendar 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 calendar days 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.

## 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.

## In the event that the dispute is not settled at mediation within 28 calendar 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 calendar 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.

1. APPLICABLE LAW

This Agreement will be governed by, and construed in accordance with, the law in force in the State or Territory in which the Institution and Other Institution are located, and each party submits to the non-exclusive jurisdiction of that State or territory and courts entitle to hear appears from those courts.

1. NOTICES

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

### delivered to the party’s address;

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

### transmitted by e-mail to the party’s 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;

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

### if transmitted by e-mail 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.

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

1. 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.

1. VARIATIONS

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

1. ASSIGNMENT

## A party may not assign its rights or obligations under this Agreement without the prior written consent of the other party.

1. 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.

1. 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.

1. 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.

1. FORCE MAJEURE

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

1. CONFLICT

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

1. GENERAL

## The Other Institution must provide evidence of compliance with its obligations under **clause 4** to the Institution on request.

## The Other Institution will not subcontract further its obligations under this Agreement without the express written permission of the Institution.

## Each party must do all things necessary or desirable to give effect to the provisions of this Agreement including by signing all documents and performing all acts.

## Each party is responsible for its own costs of entering into and performing this Agreement.

## This Agreement may be executed in any number of counterparts. All of such counterparts taken together are deemed to constitute one and the same Agreement, but all of which together will constitute one and the same Agreement.

## In the event that any signature executing this Agreement, or any part of this Agreement is delivered by facsimile transmission or by scanned e-mail delivery of a ‘.pdf’ format data file or equivalent, such signature will create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original. For execution under this clause to be valid the entire Agreement upon execution by each individual party must be delivered to the other party. For the avoidance of doubt, this Agreement may be in the form of an electronic document and may be electronically signed, if permitted by law in the jurisdiction in which the signing party is located.

## This **clause 28.7** and **clauses 1, 3.2, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15.5, 15.6, 15.7, 16, 17, 18, 19, 20** and **28.2** will survive the expiry or termination of this Agreement.

This Agreement is signed as an agreement.

Signed on behalf of **[INSERT INSTITUTION] (acting as the Sponsor) ABN: [INSERT ABN]**

Signed: ………………………………….

Name: …………………………………..

Position: …………………………………

Date: ………………………………….

Signed on behalf of the **[INSERT** **OTHER INSTITUTION] (acting through the Satellite Site(s)) ABN: [INSERT ABN]**

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: |   / /  |

**Schedule 1 - Study Details**

| **Item No.** | **Item** | **Details** |
| --- | --- | --- |
|  | Study Name: |  |
|  | Protocol Name and Number: |  |
|  | Version Number and Reviewing HREC Approval Date: |  |
|  | Principal Investigator Name and Position: |  |
|  | Address: |  |
| State: P/code:  |
|  | Satellite Site Name: |  |
|  | Associate Investigator Name: |  |
|  | Satellite Site Address: |  |
| State: P/code:  |
|  | Reviewing HREC: |  |
|  | HREC Approval Date: |  |
|  | Investigational Product: |  |
|  | Software provided by the Institution: |  |
|  | Equipment provided by the Institution: |  |
|  | Satellite Site Activities: | As specified in the Supervision Plan version **[INSERT DATE]** or as updated from time to time. |

**Schedule 2 – Particulars**

| **Item No.** | **Item** | **Detail** |
| --- | --- | --- |
| 1.
 | **Date of Agreement** | **The Date of Agreement is the date that the last party signs this Agreement** |
| 1.
 | **Completion Date** |  |
| 1.
 | **Study Title** |  |
| 1.
 | **Institution** | **[INSERT ENTITY’S LEGAL NAME]** ABN **[INSERT ABN]** located at **[INSERT PRINCIPAL ADDRESS OF BUSINESS]** |
| 1.
 | **Other Institution (acting through the Satellite Site(s))** | **[INSERT ENTITY’S LEGAL NAME]** ABN **[INSERT ABN]** located at **[INSERT PRINCIPAL ADDRESS OF BUSINESS]** |
|  | **Documents making up this Agreement and hierarchy**  | This Agreement is made up of:* + 1. the Details of the parties; and
		2. clauses 1 to 28;
		3. the Schedules; and
		4. any other document expressly incorporated by reference—

in descending order of precedence except as specified in clause 13.2, in relation to Special Conditions in Schedule 4. |

Schedule 3 - Funding

**Item 1: Information for Teletrial**

Where the Study is being conducted as a Teletrial, the Institution will make payments to the Other Institution in accordance with the agreed items in this Schedule 3.

**Item 2: Participant Related Trial Activities**

All payments for Study Participant related Study Activities (for example, visits, database entry, Study consenting, and any other Study Participant related Study Activity) as agreed between the Institution and the Other Institution, will be paid in accordance with this Schedule 3.

**Item 3: Non-Participant Related Trial Activities**

All payments relating to non-Study Participant related Study Activities (for example, start-up fees, pharmacy set up fees, administration fees) that are defined in this Schedule 3 will be paid in accordance with the Activities and amounts specified in this Schedule.

**Item 4: Teletrial Support Program funding for Other Institution**

Where the Other Institution is to receive Teletrial Support Program funding paid by the Australian Teletrial Program to the Institution, the Institution will forward that funding to the Other Institution at the next routine funds transfer period.

**Item 5: Payment Contacts and Process**

* 1. Contact details for the finance officer at each Site are specified below.

|  |  |  |
| --- | --- | --- |
|  | **Institution Finance Officer**  | **Other Institution Finance Officer**  |
| **Name and Position** |  |  |
| **Email** |  |  |
| **Phone number** |  |  |

* 1. Payments between the Institution and Other Institution will be managed as described in this Schedule 3. The Other Institution will prepare the invoice monthly for Study Participant visits from execution of this Agreement.
	2. Funds Transfer Arrangements

|  |  |
| --- | --- |
| **Describe the method by which funds will be transferred by the Institution to the Other Institution**  |  |
| **Account details for the Other Institution** |  |

**Item 6: Agreed Payments by Institution to Other Institution**

## 6.1 Non Participant Study Activities (including Data Entry, Reporting)

|  |  |
| --- | --- |
| **Description** | **Agreed Amount (excl. GST)** |
|  |  |
|  |  |
|  |  |
|  |  |

## 6.2 Participant Study Activities

|  |  |
| --- | --- |
| **Description** | **Agreed Amount (excl. GST)** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Schedule 4**

SPECIAL CONDITIONS