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| --- |
| **Clinical Trial Activities Agreement** |
| Investigator-initiated study by teletrial |
|  |
| **[Insert name of Primary Site]** **[Insert name of Satellite Site]** |

Parties

**[Insert name of Primary Site]** (ABN [insert]) of [*insert address*] Victoria (**Primary Site**)

**[Insert name of Satellite Site]** (ABN [insert]) of [*insert address*] (**Satellite Site**)

Background

A Primary Site is a Victorian public hospital which undertakes cancer research, education and treatment activities. The Satellite Site is a rural or regional health services provider.

B Primary Site has initiated the Study which will be conducted as an investigator-initiated study at various sites.

C To enable patients who are in rural or regional sites to participate in the Study, Primary Site will engage the Satellite Site to perform the Study Activities at the Site utilising a teletrials model.

D The Primary Site and the Satellite Site wish to enter this agreement to detail their arrangements regarding the conduct of the Study Activities by the Satellite Site at the Site.

# Engagement and term of agreement

# Engagement

* 1. The Primary Site engages the Satellite Site to perform the Study Activities on the terms and conditions set out in this agreement and the Satellite Site accepts that engagement.

# Term

* 1. This agreement commences on the Commencement Date and will remain in force until the End Date, unless terminated earlier or extended in accordance with this agreement.

# Study Activities

## Performance of Study Activities

* 1. The Satellite Site must perform the Study Activities in accordance with this agreement. At all times during the Term, the Satellite Site must:
		1. perform the Study Activities promptly, carefully and to the highest practicable standards;
		2. perform the Study Activities exercising all due care, skill and judgement, in an efficient and professional manner and in accordance with accepted professional and industry practices;
		3. hold all authorisations, permits and licences required under any law to perform the Study Activities; and
		4. comply with the requirements of all laws of any kind applying to the performance of the Study Activities.

## Study Activities to be conducted by Satellite Site at the Site

* 1. Without limiting clause 2.1, the Satellite Site will perform the Study Activities at the Site in accordance with:
		1. the Supervision Plan;
		2. the Protocol;
		3. any condition of the Reviewing HREC;
		4. any requirements of Regulatory Authorities;
		5. the requirements of the Australian Therapeutic Goods Administration in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or replacement and any other TGA publication or guideline that relates or may relate to clinical trials, or other such regulations or guidance governing the conduct of clinical research in the jurisdiction of the Study;
		6. the GCP Guideline; and
		7. the *National Statement on Ethical Conduct in Human Research* (2007) published by the Australian National Health and Medical Research Council.

# Obligations regarding performance of Study Activities

## Primary Site obligations

* 1. The Primary Site will perform the activities which are specified as attaching to the Primary Site in the Supervision Plan.

## Study Activities performance

* 1. In relation to its performance of the Study Activities at the Site, the Satellite Site will:
		1. ensure written approval has been obtained to conduct the Study from the Reviewing HREC prior to performance of any Study Activities and that the Study Activities are subject to the continuing oversight of the Reviewing HREC throughout their conduct;
		2. ensure that informed consent to participate in the Study is obtained from each Study Participant prior to any Study Activities being performed in relation to such Study Participant and documented using an information and consent document which has been reviewed and approved by the Reviewing HREC;
		3. complete and provide a copy to the Primary Site:
			1. any Case Report Forms created or completed by it in accordance with the requirements of the Protocol; and
			2. any other Study related materials reasonably requested by the Primary Site.

## Personnel

* 1. The Satellite Site must make available sufficient Personnel with the necessary skills, expertise, qualifications and training to carry out the Study Activities. The Satellite Site must ensure that any of its Personnel who perform the Study Activities:
		1. exercise due care, skill and judgement and perform the Study Activities in an efficient and professional manner;
		2. are competent, hold appropriate professional qualifications and hold and maintain all such practice registrations and certifications (including, where appropriate, in relation to GCP) as may be required by law;
		3. are adequately informed and instructed about the Study and in relation to the Study Activities they are required to perform; and
		4. attend an investigator meeting or a pre-Study or initiation meeting and any other meeting reasonably required by the Primary Site.

## No debarment

* 1. The Satellite Site represents and warrants that neither it, nor any of its Personnel performing Study Activities:
		1. has been debarred, disqualified or banned from conducting clinical trials or any study similar to the Study, in any jurisdiction; or
		2. is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any jurisdiction.
	2. The Satellite Site will notify the Primary Site immediately if any such investigation, disqualification, debarment, or ban occurs during the Term.

## Facilities and resources

* 1. The Satellite Site will make available adequate facilities, equipment and other resources reasonably required to perform the Study Activities, including appropriate facilities, support and systems to facilitate and enable the performance of the Study Activities by way of a teletrials or telehealth process.
	2. The Satellite Site represents and warrants that its technology and other systems which will be used to perform the Study Activities are secure, comply with all laws (including Relevant Privacy Laws) and conform to the current relevant Australian Standard (where such exists) or where an Australian Standard does not exist, to generally accepted industry standards.

**Notifications**

* 1. The Satellite Site will:
		1. immediately notify the Satellite Site of any issue relating to the safety of Study Participants, even if the issue arises after the termination or ending of this agreement;
		2. immediately notify the Primary Site of any Adverse Events and Serious Adverse Events that occur during the Study Activities in accordance with the Protocol and relevant ethical and regulatory guidelines; and
		3. promptly notify the Primary Site of any request for information made, or any other action taken, by a Regulatory Authority in relation to the conduct of the Study Activities at the Site.

## Records

* 1. The Satellite Site will create and maintain full records and documentation in relation to the Study Activities in accordance with industry standards and as required under the Protocol.
	2. The Satellite Site must retain and preserve a copy of all Created Materials, including copies of signed consent forms, Case Report Forms, Protocol, information relating to the Investigational Product, correspondence and investigator files for at least fifteen years from the End Date and in accordance with relevant laws, whichever is longer.

**Reports**

* 1. The Satellite Site will provide regular written reports to the Primary Site in relation to the Study Activities as required by the Protocol and otherwise as reasonably requested from time to time by the Primary Site.

## Satellite Site to provide information and assistance

* 1. The Satellite Site must promptly provide all information, and such other assistance, which is reasonably requested by the Primary Site from time to time to enable the Primary Site to comply with its obligations regarding the Study, including assisting the Primary Site in relation to any request, enquiry or investigation made by a Regulatory Authority regarding the conduct of the Study to the extent related to the Study Activities.

**Monitoring and audit**

* 1. The Satellite Site will allow regular monitoring visits by the Primary Site (or its delegate) and any Regulatory Authority.
	2. The Satellite Site will permit the Primary Site to audit all records related to the Institution’s performance of the Study Activities and this agreement during the Term and for a period of 3 years after the End Date.

## Improper payments

* 1. The Satellite Site warrants, represents and undertakes to the Primary Site 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 Primary Site (**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 this clause, 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.

# Investigational Product

## Supply of Investigational Product

* 1. The Primary Site will supply, or facilitate the supply, to the Satellite Site sufficient quantities of Investigational Product for the conduct of the Study Activities.

## Use of Investigational Product

* 1. The Satellite Site will use all Investigational Product made available to it for the purpose of the Study Activities in accordance with the Protocol and the directions of the Primary Site.
	2. The Satellite Site will promptly return or destroy, as requested by the Primary Site, any unused Investigational Product.
	3. The Satellite Site must:
		1. ensure that all Investigational Product made available to it for the purpose of the Study Activities is used strictly according to the Protocol or the directions of the Primary Site and is not used for any other purposes;
		2. provide a written explanation accounting for any missing Investigational Product;
		3. not charge or a Study Participant or third-party payer for Investigational Product; and
		4. keep all Investigational Product under appropriate storage conditions (including any conditions specified in the Protocol) in a secure area accessible only to authorised Personnel and ensure that complete and current records are maintained for all received, dispensed and returned Investigational Product.

## No representations or liability regarding Investigational Product

* 1. The Primary Site makes no representations and gives no warranties about whether sufficient quantities of Investigational Product will be supplied to the Satellite Site or in relation to the timing of that supply. The Primary Site will not be liable if it does not make such supply on time or at all.
	2. The Satellite Site acknowledges that the Primary Site is not the manufacturer, supplier or importer of the Investigational Product. Accordingly,
		1. The Primary Site makes no representations and gives no warranties in relation to the Investigational Product, including (but not limited to):
			1. the quality, fitness for purpose or merchantability of the Investigational Product; and
			2. that the Investigational Product is free from defects or fit for its intended purpose; and
		2. to the fullest extent permitted by law, the Primary Site excludes all liability in relation to the Investigational Product and the Institution’s use of the Investigational Product.

# Study funding

## Study Funds

* 1. In consideration of the Satellite Site performing its obligations under this agreement, the Primary Site will pay to the Satellite Site the Study Funds in the manner and on the basis of the amounts and at the times set out in Schedule 4.

# Invoices

* 1. The Satellite Site will submit to the Primary Site an invoice monthly, or as otherwise agreed by the parties.
	2. The Satellite Site will send invoices to the Primary Site to the address specified in item 1 of Schedule 4 or such other address as notified by the Primary Site to the Satellite Site.

**Payment terms**

* 1. The Primary Site will pay all invoices submitted by the Satellite Site within thirty business days of the invoice date, provided it is reasonably satisfied the relevant activities have been performed in accordance with this agreement. The Primary Site will pay all invoices submitted by the Satellite Site in Australian dollars in the manner specified in item 2 of Schedule 4.

**Payments not wages or salary**

* 1. The payments made by the Primary Site to the Satellite Site are not wages or salary. The Satellite Site is responsible for paying any tax, charge or levy that applies to the payments it receives under this agreement.

# GST

* 1. All amounts expressed in this agreement are GST exclusive. The Satellite Site warrants that it is registered under the GST Law. To the extent that the consideration to be paid or provided under this agreement is expressed to be GST exclusive, a party must also pay the GST payable on a taxable supply made to it. The party making the taxable supply must provide a tax invoice to the other party at or before the time that the other party is required to pay the GST. Terms used in this clause have the meanings given to them in the GST Law.

# Confidentiality and privacy

## Confidential information

* 1. Subject to clause 6.2, 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 a party’s respective obligations under this agreement or the conduct of the Study Activities.
	2. A party may use or disclose Confidential Information in any of the following circumstances:
		1. For complying with its internal complaint procedures, accident reporting procedures, quality assurance activities, disciplinary procedures or any applicable policy in relation to patient safety, Adverse Events or Serious Adverse Events and/or reportable incidents.
		2. For disclosing any material risks identified during the Study or Study Activities or subsequent to it or them, to Study Participants, Study researchers, medical practitioners administering treatment to Study Participants, relevant human research ethics committees and regulatory authorities and government agencies.
		3. For complying with the requirements of any Regulatory Authority or government agency.
		4. For monitoring of the Study or the Study Activities by the Reviewing HREC.
		5. Where the party which owns the Confidential Information consents in writing to the disclosure.
		6. Where the Confidential Information has been independently received from a third party who is free to disclose it.
		7. Where the Confidential Information has been developed by or for the receiving party independently of the Confidential Information disclosed under this agreement.
		8. Where the Confidential Information has entered the public domain other than as a result of a breach of this agreement.
		9. Where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the other party.
		10. For the purpose of legal advice.
		11. For the purpose of a disclosure to its insurer.
	3. The Primary Site may disclose the terms of this agreement and any Confidential Information of the Satellite Site to any other party involved in the funding or conduct of the Study, to the extent such disclosure is required in relation to the conduct of the Study and for the Primary Site to perform any obligation regarding the conduct of the Study.

**Disclosures to Personnel**

* 1. Each party may disclose the Confidential Information of the other to their Personnel requiring access to the Confidential Information for performing any respective obligations under this agreement.

**Period of confidentiality**

* 1. The obligations set out in clauses 6.1 to 6.4 (inclusive) will remain in effect during the Term and for a period of five years following termination or expiration of this agreement.

**Return of Confidential Information**

* 1. A receiving party will at the written request of the disclosing party, upon termination of this agreement return all the disclosing party's Confidential Information to the disclosing party or destroy all such Confidential Information in its or their possession, subject to any applicable retention requirements imposed by law or its insurer.

## Privacy

* 1. The parties must ensure that any Personal Information collected, received or arising in connection with this agreement, including but not limited to Personal Information of a party’s Personnel and of Study Participants, is collected, stored, used and disclosed in accordance with Relevant Privacy Laws.
	2. The Satellite Site agrees that the Primary Site may use and disclose the Personal Information of the Institution’s Personnel for any purpose related to the Study and this agreement and the Satellite Site will obtain the consent of its Personnel in relation to such use and disclosure.
	3. The Satellite Site must promptly notify the Primary Site of any loss of, or unauthorised use or disclosure of, Personal Information relating to a Study Participant or the Primary Site Personnel (**Data Breach**) of which it becomes aware. The Satellite Site must provide all reasonable assistance to the Primary Site so that the Primary Site can satisfy its obligations regarding any Data Breach.

# Intellectual Property and Publications

## Ownership of Background Intellectual Property

* 1. Each party acknowledges and agrees that all rights in any Background Intellectual Property which is provided by a party to the other in connection with this agreement remain the property of that party. Subject to clause 7.2, nothing in this agreement confers on a party any right, title or interest in or in respect of any Background Intellectual Property of the other party.

## Institution’s Background Intellectual Property

* 1. The Satellite Site grants to the Primary Site a world-wide, non-exclusive, irrevocable, perpetual, royalty free and licence fee free licence to use (including the right to sub-licence) the Institution’s Background Intellectual Property for any purpose connected with the conduct of the Study, for further research related to the Study, for Publication purposes and for the commercialisation of the Created Materials.

## Ownership of Created Materials

* 1. All Intellectual Property in the Created Materials will vest automatically upon its creation in the Primary Site and the Satellite Site presently assigns to the Primary Site all existing and future Intellectual Property rights (including all future copyright) contained in the Created Materials. The Satellite Site agrees to execute or procure the execution by its Personnel of any documents reasonably necessary to give effect to this assignment.
	2. The Satellite Site must promptly disclose to the Primary Site all Intellectual Property rights the Satellite Site creates or develops in the course of this agreement.
	3. The Satellite Site must not, and must ensure its Personnel do not, use or disclose the Created Materials for any purpose, other than in accordance with this agreement.
	4. Without limiting clause 7.3, the Satellite Site must procure that all of its Personnel who create any Intellectual Property in connection with this agreement or the Study activities sign an agreement whereby they irrevocably consent to all acts or omissions by the Primary Site that may otherwise constitute an infringement of their ‘moral rights’ (as that term is defined in the *Copyright Act 1968* (Cth)).

## Publications

* 1. The Satellite Site will ensure notification and consultation with participating parties, including the VCCC, prior to distributing any publicity, including articles, news release or other public announcement, or representations, written or verbal, whether to the public press or otherwise, relating to this agreement, the Study Activities or the Study.

## Publicity and announcements

* 1. The Satellite Site will not make or cause to be made any publicity, publish any articles, news release or other public announcement, or make any representations, written or verbal, whether to the public press or otherwise, relating to this agreement, the Study Activities or the Study, without the Primary Site’s prior written consent.

## Use of Names

* 1. Except as required by applicable laws, a party will not use another party’s or their Affiliates' names, logos, trademarks or products in any public statement, advertising, public relations or promotional material, without the prior approval of the other party.

# Liability and indemnity

# Liability

* 1. Subject to clause 8.2, to the extent permitted by law, the total liability of the Primary Site, its Related Entities, and their respective directors, officers and Personnel in respect of any and all defaults of any obligations under this agreement or otherwise at law is limited to the amount of the Study Funds in aggregate.
	2. The Primary Site, its Related Entities, and their respective directors, officers and Personnel will not be liable (including without limitation, in tort or contract) for any indirect, consequential or special loss, damage, cost or expense of any kind including but not limited to loss of savings and profit suffered or incurred by the Satellite Site in connection with this agreement.

## Release and indemnity

* 1. The Satellite Site releases and indemnifies, and will continue to release and indemnify, the Primary Site, its Related Entities and their respective directors, officers and Personnel from and against all actions, claims, demands, costs and expenses (including the costs of defending or settling any action, claim or demand) made, sustained, brought or prosecuted in any manner directly based upon, occasioned by or attributable to any injury to any person (including death) or loss of or damage to property (including any infringement of Intellectual Property rights) which may arise in relation to:
		1. any intentional, unlawful or negligent act or omission of the Satellite Site or its Personnel under this agreement or in connection with the conduct of the Study Activities by the Satellite Site or its Personnel; and
		2. any breach of the terms and conditions of this agreement by the Institution,

except to the extent the action, claim, demand, cost or expense is caused by an unlawful or negligent act or omission of the Primary Site, its Related Entities and their respective directors, officers and Personnel.

# Insurance

## Parties to maintain insurance

* 1. The Satellite Site 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 Activities or performing its obligations under this agreement.
	2. The Satellite Site satisfies the requirements of clause 9.1 if it is a Victorian Public Entity.
	3. If the Satellite Site is not a Victorian Public Entity it must maintain insurance cover which:
		1. is issued on an occurrence made basis, or if issued on a claims made basis it must meet the further requirements of clause 9.4;
		2. is continuously maintained throughout the period of the conduct of the Study, subject to clause 9.4;
		3. contains a minimum limit of indemnity of $20 million for any one claim, $20 million for any one event and $20 million in the aggregate for any one year (or such other amount as may be reasonably specified by the Primary Site from time to time);
		4. contains a deductible or self-insured retention amount no greater than $25,000 for any one claim or event;
		5. provides cover for professional indemnity and medical indemnity liability;
		6. provides indemnity in relation to liabilities arising from the conduct of human clinical trials, including the Study Activities;
		7. provides indemnity in respect of injury, loss or damage arising from the use of equipment involving the emission of ionising radiation; and
		8. does not exclude risks relating to Human Immune-deficiency Virus or Acquired Immune Deficiency Syndrome.
	4. If an Satellite Site is not a Victorian Public Entity and chooses an insurance policy written on a claims made basis, then it must maintain the policy or policies for at least 7 years after the End Date, or alternatively, obtain run-off cover which has the same effect if the business has ceased.
	5. The Satellite Site will provide written evidence which is reasonably acceptable to the Primary Site of its insurance arrangements within 5 business days of a request made by the Primary Site.

# Termination

## Termination by either party

* 1. Either party may terminate this agreement with fifteen business days’ prior written notice or such shorter time period as is reasonably required in the circumstances if the other party:
		1. breaches any provision of this agreement and fails to remedy the breach (where it is capable of remedy) within 15 business days of a written notice from the first party specifying the breach and requiring its remedy. For the avoidance of doubt, the Primary Site’s failure to pay a disputed invoice does not constitute a breach of this agreement; or
		2. suffers an Insolvency Event.

## Termination by the Primary Site

* 1. The Primary Site may:
		1. terminate this agreement at any time after the Commencement Date by giving at least 60 calendar days’ notice to the Institution; and
		2. immediately terminate this agreement by giving written notice to the Satellite Site if any agreement entered between the Primary Site and any third party regarding the Study (including funding of the Study) is terminated for any reason.

## Termination for safety reasons

* 1. The Primary Site may terminate this agreement immediately by written notice to the Satellite Site if it has formed the opinion, based on reasonable grounds and evidence, that continuing the Study Activities poses an unacceptable risk to the rights, interests, safety or well-being of Study Participants.

# Obligations upon ending or termination of this agreement

* 1. Upon termination of this agreement, the Satellite Site must cease performing the Study Activities, subject to clause 10.5.1.
	2. In the event of early termination of this agreement, the following will apply:
		1. The Satellite Site will conduct an orderly closure of the Study Activities and will ensure that the health and safety of Study Participants is not compromised by the early ending of the Study Activities and that Study Participants who may be affected by termination receive adequate medical care.
		2. The Satellite Site must not perform any Study Activities for which payment would otherwise be required to be made by the Primary Site without the prior written approval of the Primary Site.
		3. Unless this agreement is terminated pursuant to clause 10.1, the Primary Site will pay the Satellite Site for Study Activities performed up until the date of termination calculated in accordance with Schedule 3.
		4. Subject to any applicable retention requirements imposed by law, the Satellite Site will submit to the Primary Site all records, material and reports created (or required to be created) under this agreement, including any Case Report Forms it has created or completed.
		5. Subject to Relevant Privacy Laws, the Satellite Site will provide to the Primary Site reasonable access to any Study Activities files and Site master files as the Primary Site may require for a period of 3 years after the ending or termination of this agreement. Such access will be subject to any reasonable requirements of the Satellite Site regarding privacy, confidentiality, security and occupational health and safety.

**Clauses surviving expiration or termination of agreement**

* 1. The following clauses will survive the expiration or termination (for whatever reason) of this agreement:
		1. clauses 3.9 to 3.14;
		2. clause 4.6;
		3. clause 5 (Study funding);
		4. clause 6 (Confidentiality and privacy);
		5. clause 7 (Intellectual Property and Publications);
		6. clause 8 (Liability and Indemnity);
		7. clause 9 (Insurance);
		8. clauses 10.4, 10.5 and 10.6 (Obligations at end of agreement);
		9. clause 12 (Dispute resolution);
		10. clause 13 (Notices);
		11. clause 14.11 (Governing law); and
		12. any clause which states it will survive, or its obligations endure beyond, the expiration or termination of this agreement.

# Parties’ representatives

# Primary Site Representative

* 1. The Primary Site appoints the Primary Site Representative as its duly authorised representative under this agreement. Any notice, information or communication given or made to the Primary Site Representative will be deemed to have been given or made to the Primary Site.
	2. The Primary Site must give written notice to the Satellite Site immediately if its representative is removed or replaced, together with the details of its new representative.

# Satellite Site Representative

* 1. The Satellite Site appoints the Satellite Site Representative as its duly authorised representative under this agreement. Any notice, information, instruction or other communication given or made to the Satellite Site Representative will be deemed to have been given or made to the Institution.
	2. The Satellite Site must give written notice to the Primary Site immediately if its representative is removed or replaced, together with the details of its new representative.

**Responsibilities of Representatives**

* 1. Each party’s representative will be responsible for the day to day administration of this agreement on behalf of the party appointing them. The representatives must be available and able to be contacted during normal business hours.

# Dispute resolution

## Procedures to be followed

* 1. If a dispute arises in connection with this agreement, the parties will adhere to the following procedures.
	2. In the first instance two representatives of each party shall meet and endeavour to resolve the dispute in an expeditious and informal manner. If resolution is not achieved within fifteen business days, then the chief executive officer (or equivalent) of each of the parties or delegate shall meet to resolve the dispute.
	3. If resolution is not achieved within ten business days of the chief executive officer (or equivalent) of each of the parties meeting, then either party may give the other a dispute notice requiring that the dispute be resolved in accordance with this clause 12.
	4. If a dispute notice is issued, an attempt shall be made to resolve the dispute with the help of a mediator to be appointed jointly by the parties. If the parties do not agree on a mediator within fifteen business days after the notice is given, the mediator is to be appointed by the then current President of the Law Society of the State or Territory in which the Primary Site is located. Each of the parties must co-operate fully with the mediator and will pay an equal share of the fees and expenses the mediator is entitled to. If the dispute is not resolved within twenty business days of the mediator being appointed, the mediation shall cease and any party may then commence legal proceedings.

## Parties to cooperate

* 1. The parties shall cooperate to ensure that these procedures are carried out expeditiously.

## Interlocutory relief

* 1. Clause 12 does not restrict or limit the right of either party to obtain interlocutory relief, or to immediately terminate this agreement where this agreement provides such a right.

# Notices

## Giving notice

* 1. Any notice (which includes, without limitation, a demand, request, consent, approval and any other communication made, required or authorised under this agreement) given under this agreement must be:
		1. in writing;
		2. directed to the recipient’s address specified in Schedule 1, as varied by any notice; and
		3. hand delivered or sent by prepaid post, facsimile or email to that address.

## Receipt of notice

* 1. A notice given in accordance with clause 13.1 is taken to be received by the recipient:
		1. if hand delivered, on delivery;
		2. if sent by prepaid post, four business days after the date of posting; or
		3. if sent by facsimile, when the sender’s facsimile system generates a message confirming successful transmission of the total number of pages of the notice unless, within eight business hours after that transmission, the recipient informs the sender that it has not received the entire notice; or
		4. if sent by email, on the day of transmission provided that the sender can give evidence of transmission and the intended recipient does not give evidence of non-receipt.

 In all cases, a notice received after 5:00 pm in the place of receipt or on a day that is not a business day is taken to be received by the recipient at 9:00 am on the next business day.

## Signing of notice

* 1. A notice given under this agreement is sufficiently signed if:
		1. in the case of a corporation, it is signed by a director, secretary or other officer of the corporation; or
		2. in the case of an individual, it is signed by that individual.

## Other modes of service permitted

* 1. The provisions of this clause are in addition to any other mode of service permitted by law.

# General

## Subcontracting

* 1. The Primary Site may subcontract any of its obligations under this agreement.
	2. The Satellite Site must not subcontract any of its obligations under this agreement without the prior written consent of the Primary Site, which consent may be withheld in the Primary Site’s absolute discretion.

# Assignment and novation

* 1. The Satellite Site party must not transfer, assign or novate this agreement or any part of this agreement without the prior written consent of the Primary Site, which consent may be withheld in the Primary Site’s absolute discretion.

## Force majeure

* 1. 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, 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 thirty business days each party may, by written notice to the others, terminate this agreement.

## Priority

* 1. In the event of an inconsistency, this agreement is to be interpreted in accordance with the following order of priority:
		1. first, by reference to the terms and conditions set out in the body of this agreement;
		2. second, by reference to the terms of the Schedules; and
		3. finally, by reference to any other documents or information incorporated by reference into this agreement.

## Preferred construction

* 1. The parties agree that a construction of this agreement that results in all provisions being enforceable is to be preferred to any other construction.

## Severance

* 1. If, despite the application of clause 14.6, any clause or part of a clause is illegal, unenforceable or invalid, that clause or part is to be treated as removed from this document, but the rest of this document is not affected.

# Enforcement of indemnity

* 1. A party can enforce its rights of indemnity under this agreement without first incurring any expense or making any payment.

# Entire agreement

* 1. This agreement constitutes the entire agreement between the parties in relation to their respective obligations concerning the Study and replaces any prior arrangements, agreements, representations or undertakings.

## Variation

* 1. Any variation to this agreement must be in writing and signed by the parties.

# Governing law

* 1. This agreement is governed by the law of the State of Victoria, Australia and each party submits to the exclusive jurisdiction of the courts of that State. The parties will not object to the exercise of jurisdiction by those courts on any basis.

# Separate documents

* 1. This agreement is properly executed if each party executes either this document or an identical document. In the latter case, this document takes effect when the separately executed documents are exchanged between the parties.

# Waiver

* 1. No right under this agreement is waived or deemed to be waived except by notice in writing signed by the party waiving the right. A waiver by any party in respect of any breach of a condition or provision of this agreement will not be deemed to be a waiver in respect of any other breach.
	2. Failure or delay by any party to enforce any provision of this agreement will not be deemed to be a waiver by that party of any right in respect of any other such breach.

# Costs

* 1. Except as otherwise set out in this agreement, each party must pay its own costs in relation to preparing, negotiating and executing this agreement and any document related to this agreement.

## Further acts

* 1. The parties must promptly do and perform all acts and things and execute all documents as may from time to time be required, and at all times will act in good faith, for the purposes of or to give effect to this document.

## Party preparing document not to be disadvantaged

* 1. No rule of contract interpretation must be applied in the interpretation of this agreement to the disadvantage of one party on the basis that it prepared or put forward this agreement or any document comprising part of this agreement.

## No agency or partnership

* 1. The relationship between the parties is that of principal and independent contractor. No party is an agent, representative or partner of any other party by virtue of this document. The Satellite Site must not represent itself as an agent, representative or partner of the Primary Site in any circumstances.

## No authority to act

* 1. No party has any power or authority to act for or to assume any obligation or responsibility on behalf of another party, to bind another party to any agreement, negotiate or enter into any binding relationship for or on behalf of another party or pledge the credit of another party except as specifically provided in this document or by express agreement between the parties.

## Time for action

* 1. If the day on or by which something is required to be done or may be done is not a business day, that thing must be done on or by the next business day.

## Name and logos

* 1. A party must not use the other party’s name, logo or brand in any way without the prior written permission of the other party.

# Definitions and Interpretation

## Definitions

* 1. In this agreement, unless the contrary intention appears:

**Adverse Event** means any untoward medical occurrence in a patient or clinical investigation subject administered the Investigational Product and which does not necessarily have a causal relationship with this treatment. An Adverse Event includes any unfavourable and unintended sign, symptom, or disease temporally associated with the use of the Investigational Product, whether or not related to the Investigational Product.

**Background Intellectual Property** means any information, techniques, inventions, discoveries, methods, systems, know-how, software and materials (regardless of the form or medium in which they are disclosed or stored) that are provided by one party to the other party for use in the conduct of the Study or the Study Activities which is:

 (a) in existence as at the Commencement Date; or

 (b) created, developed or generated by a party after the Commencement Date other than in the course of or incidental to performing any of its obligations under this agreement.

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

 **Commencement Date** means the commencement date specified in Schedule 1.

 **Confidential Information** means:

 (a) in respect of the Primary Site:

 (i) the Protocol and information relating to the Investigational Product;

 (iii) information, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Primary Site;

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

 (v) information concerning their business affairs or clients;

 (vi) all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Site or elsewhere;

 (b) in respect of the Institution:

 (i) information in relation to the Institution’s business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors; and

 (ii) 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.

 but Confidential Information does not include Personal Information.

 **Created Materials** means all the materials, data, results, outputs and information, including Case Report Forms, created by the Satellite Site in performing the Study Activities or in connection with this agreement.

 **End Date** means the end date specified in Schedule 1.

 **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.

 **GST** means tax that is payable under the GST Law and imposed as goods and services tax.

 **GST Law** means any law relating to GST including *A New Tax System (Goods and Services Tax) Act 1999* (Cth).

 **Insolvency Event** means anything that reasonably indicates that there is a significant risk that that person is or will become unable to pay its debts as they fall due, including without limitation:

 (a) a meeting of the person’s creditors being called or held;

 (b) a step being taken to make the person bankrupt;

 (c) the appointment of a controller or administrator as defined in section 9 of the *Corporations Act 2001* (Cth);

 (d) the person entering into any type of arrangement with, or assignment for the benefit of all or any of its creditors;

 (e) the person being made subject to a deed of company arrangement; or a step being taken to have a receiver, receiver and manager, liquidator or provisional liquidator appointed to the person or any of its assets; and

 (f) the person is declared insolvent.

 **Satellite Site Representative** means the Satellite Site representative specified in Schedule 1, or other person from time to time appointed by the Satellite Site and notified to the Primary Site to be the Satellite Site Representative for the purposes of this agreement.

 **Intellectual Property** means all industrial and intellectual property rights, including without limitation:

 (a) patents, copyright, future copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders’ rights, registered designs, registered and unregistered trade marks, know how, trade secrets and the right to have confidential information kept confidential, any and all other rights to intellectual property which may subsist anywhere in the world; and

 (b) any application or right to apply for registration of any of those rights.

 **Investigational Product** means the medicine(s) being trialled or tested in the Study which is specified in Schedule 1 and includes, where the context requires, any placebo.

 **Personal Information** means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

**Personnel** means employees, agents, contractors and/or authorised representatives.

**Protocol** means the document described and set out in Schedule 5.

**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 Created Materials, in printed, electronic, oral or other form. **Publication** has a corresponding meaning.

**Regulatory Authority** means any government body which has jurisdiction over the conduct of the Study and includes the Australian Therapeutic Goods Administration.

**Related Entity** means an associate of the person for the purposes of sections11 to 16 (inclusive) of the *Corporations Act 2001* (Cth).

 **Relevant Privacy Laws** means the *Health Records Act 2001* (Vic), the *Privacy and Data Protection Act 2014* (Vic) and any other legislation, code or guideline which applies in the jurisdiction in which the Primary Site is located and which relates to the protection of Personal Information.

 **Reviewing HREC** means the human research ethics committee reviewing the Study on behalf of the Institution.

 **Primary Site Representative** means the Primary Site representative specified in Schedule 1, or other person from time to time appointed by the Primary Site and notified to the Satellite Site to be the the Primary Site Representative for the purposes of this agreement.

 **Serious Adverse Event** means any untoward medical occurrence that at any dose:

 (a) results in death;

 (b) is life-threatening;

 (c) requires in-patient hospitalisation or prolongation of existing hospitalisation;

 (d) results in persistent or significant disability/incapacity; or

 (e) is a congenital anomaly/birth defect.

 **Site** means the means the location(s) under the control of the Satellite Site where the Satellite Site actually conducts the Study Activities.

 **Study** means the research study which is described in Schedule 1.

 **Study Activities** means the services and activities the Satellite Site must perform under this agreement, including those specified in Schedule 2.

 **Study Funds** means the rates, charges and costs set out in Schedule 4.

 **Study Participant** means a person recruited by the Satellite Site to participate in the Study or a person on or in respect of whom any Study Activities are performed.

 **Supervision Plan** means the plan set out in Schedule 3.

 **Term** means the period during which this agreement remains in force.

 **Victorian Public Entity** means a body, entity or agency incorporated pursuant to the *Health Services Act 1988* (Vic) and which is an insured under a program or scheme of insurance that is arranged by the Victoria Managed Insurance Authority.

## Interpretation

* 1. In this agreement, except where the context otherwise requires:
		1. a reference to a person or body includes a government agency, partnership, trust, joint venture, association, corporation or a body corporate;
		2. clause headings are for convenience only and are not intended to affect the interpretation of this agreement;
		3. where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;
		4. words in the singular include the plural and vice versa;
		5. all the provisions in any schedule to this agreement are incorporated in, and form part of, this agreement;
		6. if a period of time is specified and dates from a given day or the day of an act or event, it is to be calculated inclusive of that day;
		7. a reference to a monetary amount means that amount in Australian currency;
		8. a reference to any law or legislation includes any statutory amendment or re-enactment, and any subordinate legislation or regulations issued there under;
		9. a reference to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced from time to time;
		10. a reference to a recital clause or schedule, is a reference to a recital, clause or schedule in this document;
		11. a reference to a business day means a day on which all banks are open for business generally in Melbourne, Victoria; and
		12. a covenant or agreement on the part of two or more persons binds them jointly and severally.

## Execution

**Executed** as an agreement

Date:

|  |  |
| --- | --- |
| Signedfor and on behalf of **Primary Site** by its authorised officer in the presence of:...................................................Signature of witness………………........…………………........Name of witness | ...................................................Signature of authorised officer………………........…………………........Name of authorised officer |

|  |  |
| --- | --- |
| Signed for and on behalf of [insert name of Institution] by its authorised officer in the presence of:........................................................Signature of witness……………………………………………………Name of witness | ………………........………………….......…Name of authorised officer...............................................Signature of authorised officer |

## Schedule 1

|  |
| --- |
| **Commencement Date** (clause 1.2)[*Insert*] |
| **End Date** (clause 1.2)[*Insert*] |
| **Study**[*Insert*] |
| **Investigational Product** (clause 4)[*Insert*] |
| **Primary Site Representative** (clause 11.1)[*Insert* |
| **Satellite Site Representative** (clause 11.3)[*Insert* |
| **Notices** (clause 13)**Primary Site**[*Insert*]**Satellite Site** [*Insert*] |

## Schedule 2 – Study Activities

[insert details]

## Schedule 3 – Supervision Plan

[*insert*]

## Schedule 4 – Study Funds

[*Insert details of Study funds*.]

**1 Address for invoices**

The Satellite Site will send invoices to the following address of Primary Site:

 *[Insert address]*

 *Attention: [Name]*

**2 Manner in which the Primary Site is to pay**

The Primary Site will make all payments required under this agreement in the following manner:

By cheque addressed to:

 [*Insert details*]

 ;or

By electronic transfer into the following account(s):

[*Insert account details*]

## Schedule 5 - Protocol

**Title:** [*insert*]

**Date:** [*insert*]

The VCCC Teletrials Program is supported by the Victorian Government.

