**CLINICAL TRIAL RESEARCH AGREEMENT SUBCONTRACT**

**FOR STUDIES CONDUCTED UNDER A TELE-TRIALS MODEL**

This Agreement is made on the day of 20

**BETWEEN:** The Institution so described in **Schedule 1** (the **‘Institution’**)

**AND:** The **Subcontractor** so described in **Schedule 1** (**‘Subcontractor’**)

**RECITALS**

1. The Institution is bound by applicable legislation in its jurisdiction as a provider of health services to the public.
2. The Institution has been engaged by the Sponsor to perform the Study under the Head Agreement.
3. The Institution seeks for the Subcontractor to perform activities on its behalf for the Study.
4. The Parties agree to perform their respective activities relating to the Study as set out in this Subcontract.
5. DEFINITIONS AND INTERPRETATION
	1. **Definitions**

The definitions in the Head Agreement apply to this Subcontract in context except for the following definitions:

**Activities** means the subcontracted activities described in **Item 7** of **Schedule 1**.

**Certificate of Insurance** means the certificate of insurance required pursuant to **clause 15** in the manner so described in **Schedule 4**;

**Commencement Date** means the date so described in **Item 1** of **Schedule 1**, but if such date is earlier than the date of commencement of the Head Agreement, then the Commencement Date will be deemed to be the date of commencement of the Head Agreement.

**Completion Date** means the date so described in **Item 2** of **Schedule 1**.

**Head Agreement** means the clinical trial research agreement between the Institution and the Sponsor attached as **Schedule 3**, excluding the portions thereof relating to the financial arrangements between the Sponsor and the Institution.

**HREC Approval** means the approval to conduct the Study given by the Reviewing HREC, as amended from time to time by the Reviewing HREC.

**Party** means each of the Institution and the Subcontractor.

**Schedule** means a document referenced in this Subcontract and described as a schedule to this Subcontract.

**Sponsor** means the sponsor who is a party to the Head Agreement.

**Study** means the Study as described in **Item 3** of **Schedule 1**.

**Subcontract** means this document and all annexures, attachments and schedules incorporated by reference.

**Subcontractor** means the organisation so described in **Item 5** of **Schedule 1**.

**Subcontractor’s Confidential Information** means information in relation to the Subcontractor’s business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors, but does not include Personal Information.

**Subcontractor’s Investigator** is the person employed or engaged by the Subcontractor responsible for the conduct of the Activities, as described in **Item 6** of **Schedule 1**.

* 1. **Interpretation**
		1. In this Subcontract, the clause headings have been inserted for ease of reference only and are not intended to affect the meaning or interpretation of this Subcontract.
		2. The rules that apply in interpreting this Subcontract are those that are referenced in the relevant clause 1.2 of the Head Agreement.
1. TERM
	1. This Subcontract commences on the Commencement Date and will continue until the Completion Date unless terminated earlier in accordance with this Subcontract.
	2. The Parties may extend the Completion Date by mutual written agreement.
2. NATURE OF THIS SUBCONTRACT
	1. This document constitutes a subcontract permitted under the Head Agreement and the Institution remains responsible to the Sponsor under the Head Agreement for its subcontracted obligations and is liable to the Sponsor under the Head Agreement for all acts and omissions of the Subcontractor as if they were the Institution’s acts and omissions in accordance the Head Agreement.
3. SUBCONTRACTED ACTIVITIES
	1. The Subcontractor will perform the Activities in accordance with:
		1. the Protocol;
		2. the terms of the Head Agreement applicable to the Institution which apply to those Activities;
		3. the principles of good scientific and clinical research practices;
		4. all applicable local, State and Federal laws, legislation, regulations, rules and by-laws; and
		5. the TGA approval for the Study, the HREC Approval and all relevant Reviewing HREC directions issued from time to time.
4. INVESTIGATIONAL PRODUCT
	1. Where the Subcontractor’s pharmacy will handle and dispense medicine(s) constituting an Investigational Product, it will:
		1. use the medicine(s) solely for the Study and not for any other purpose;
		2. abide by the same obligations and responsibilities as the Institution’s pharmacy under the Head Agreement; and
		3. dispose of, or destroy, the medicine(s) in accordance with the instructions of the Institution and the instructions of the Sponsor communicated by the Institution, and in accordance with applicable laws, regulations and the Institution’s policies and procedures.
5. MEETINGS
	1. The Subcontractor’s Investigator for the Study will meet with each other investigator 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.
6. MONITORING VISITS AND REGULATORY AUTHORITIES
	1. Subject to **clause 11**, the Subcontractor will allow regular monitoring visits in accordance with the same terms as those applicable to the Institution under the Head Agreement.
	2. If the Subcontractor 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 Subcontractor 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 Subcontractor or its Personnel.
	4. The Subcontractor:
		1. warrants that it is not and has 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
		2. will promptly notify both the Institution and Sponsor 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.
7. RECORDS AND INTELLECTUAL PROPERTY
	1. The Subcontractor must:
		1. retain and preserve a copy of all Study Materials in accordance with the same terms as those applicable to the Institution under the Head Agreement;
		2. ensure that no Study Materials are destroyed before the expiration of the time period specified in the Head Agreement without the prior written approval of the Institution; and
		3. 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.
	2. The Institution grants to the Subcontractor and its Personnel the same rights to use the Background IP and Study Materials as granted to the Institution under the Head Agreement and on the same conditions (except for the right to sub-license or transfer) for the purposes of the Study.
	3. The Subcontractor grants to the Institution and the Sponsor a licence to that Subcontractor’s Background IP on the same terms as the licence granted by the Institution to the Sponsor to the Institution’s Background IP as specified in the Head Agreement.
	4. All Intellectual Property in the Study Materials created by the Subcontractor will vest automatically upon its creation in the Sponsor on the same terms as those applicable to the Institution under the Head Agreement. The Subcontractor 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.
	5. The Subcontractor must promptly disclose and communicate in writing to the Sponsor full particulars of any Intellectual Property that the Subcontractor or its Personnel make, discover or conceive in the course of the Study that is directly related to the Study Materials.
8. PAYMENTS AND INVOICING
	1. The terms and conditions under this Subcontract for the payment and invoicing between the Parties of any fees in relation to the Study are specified in **Schedule 2**.
	2. The making of any payment is conditional on the provision of a valid tax invoice in accordance with GST Law.
9. PERSONNEL
	1. The Subcontractor warrants that each person engaged by it to perform any part of the Activities:
		1. is competent;
		2. has the necessary and appropriate qualifications, licenses, admissions, memberships and skills to ensure they are both qualified and able to perform the relevant activities; and,
		3. 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.
	2. The Subcontractor 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.
	3. The Subcontractor must give written notice to the Institution promptly upon becoming aware that it no longer complies with the warranties and assurances provided in this clause.
10. CONFIDENTIALITY
	1. Subject to **clause 11.2**, the Subcontractor must not, and must ensure its Personnel do not, use or disclose any Confidential Information of the Institution or the Sponsor, other than where, and only to the extent that, such use or disclosure is necessary for the performance of the Activities, the exercise of its rights or the performance of its obligations under this Subcontract.
	2. The Subcontractor may only use or disclose the Institution’s Confidential Information to the extent necessary to comply with the Subcontractor’s obligations under this Subcontract.
	3. The Subcontractor may only use or disclose Sponsor’s Confidential Information for the purposes and on the conditions applicable to the Institution in respect of the Sponsor’s Confidential Information under the Head Agreement.
	4. The Institution or Sponsor may disclose the Subcontractor’s Confidential Information:
		1. on a need to know and confidential basis to their Affiliates and otherwise as required for the conduct of the Study or the performance of its obligations under the Head Agreement or this Subcontract;
		2. on a need to know and confidential basis to other like subcontractors as required for the conduct of the Study; or
		3. if required by law, with notice as soon as reasonably practical to the Subcontractor, and subject to the Institution or Sponsor upon request providing reasonable assistance to enable the Subcontractor to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure at the Subcontractor’s cost.
	5. Each Party is responsible for ensuring that its Personnel are aware of the obligations in respect of Confidential Information in this clause and the Head Agreement, and are bound in similar terms to keep such information confidential.
	6. Information will not be Confidential Information where it satisfies the requirements of the Head Agreement to not be Confidential Information.
11. PRIVACY
	1. The Subcontractor must ensure that any Personal Information of Study Participants or Personnel it obtains or holds as a result of the conduct of the Study is collected, stored, used and disclosed by it in accordance with the Relevant Privacy Laws.
	2. The Subcontractor will promptly report to the Institution any unauthorised access to, use or disclosure of Personal Information of Study Participants (**‘Incident’**) of which it becomes aware, and will work with the Institution to take reasonable steps to remedy the Incident.
	3. The Subcontractor agrees that the Institution may collect, use and disclose routine work-related Personal Information regarding the Subcontractor’s Personnel in connection with the Study, such as names, titles and business contact information (**‘Subcontractor Personnel Information’**) and may provide that information to the Sponsor and the Sponsor’s business partners and vendors working with Sponsor on matters related to the Study, who may collect, use and disclose such information, solely for the following purposes:
		1. compliance with laws and regulations regarding possible financial conflicts of interest;
		2. assessment of Personnel qualifications to conduct the Study;
		3. Study quality control and management; or
		4. to relevant ‘human research ethics committees’ (as that term is defined in the NHMRC Statement on Ethical Conduct in Human Research (2007) or its current replacement) Regulatory Authorities in connection with their performance of review or oversight responsibilities for the Study.
	4. Where required, the Subcontractor will notify, and obtain the consent of, its relevant Personnel for the use and disclosure of their Personal Information included in Subcontractor Personnel Information for the purposes described in this clause.
	5. The Subcontractor acknowledges that the Head Agreement obliges Sponsor to comply with the Relevant Privacy Laws applicable to it regarding its collection, storage, use and disclosure of Subcontractor Personnel Information.
12. PROMOTIONAL MATERIAL AND ANNOUNCEMENTS
	1. Subject to **clause 13.2**, each Party will not use the name or names of other Party, the Sponsor, or their Personnel in any advertising or sales promotional material or in any Publication without prior written permission from the other Party.
	2. Institution and Sponsor may disclose that the Subcontractor is involved in the Study, the type of services performed by the Subcontractor, and the existence and terms of this Subcontract only where required for compliance with applicable laws and regulations, industry codes of practice or as otherwise specified in the Head Agreement.
13. SECURITY
	1. The Subcontractor represents and warrants that consistent with the corresponding obligations of the Institution specified in the Head Agreement that:
		1. 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 ‘health information’ as that term is defined under Relevant Privacy Laws; and
		2. 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.
14. INSURANCE
	1. The Subcontractor warrants that it has, or will:
		1. effect and maintain professional indemnity and public liability insurance in accordance with **Item 1** of **Schedule 4**; and
		2. on request by the Institution, provide a Certificate of Insurance in accordance with **Item 2** of **Schedule 4**.
	2. This claus**e 15** continues in operation for so long as any obligations remain in connection with this Subcontract.
15. LIABILITY
	1. The Subcontractor is liable for its own acts and omissions except those expressly indemnified by the Sponsor.
16. ANTI-BRIBERY / ANTI-CORRUPTION
	1. The Subcontractor 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 Subcontract or to otherwise obtain an improper advantage for the Subcontractor, the Institution or Sponsor (**‘Improper Payment’**), and has not received an Improper Payment, and will not offer, promise, pay, authorise or receive any Improper Payment in the future. For the purposes of this **clause 17**, 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.
17. TERMINATION
	1. The Institution may terminate this Subcontract in respect of a given Subcontractor for breach of this Subcontract by that Subcontractor, in the case of breach of **clause 17** – by immediate notice, and in any other case, provided that it gives thirty (30) days prior notice of the breach to the relevant Subcontractor and that breach is not rectified within that period.
	2. The Subcontractor may terminate this Subcontract for breach of this Subcontract by the Institution provided that it gives thirty (30) days prior notice of the breach to the Institution and that breach is not rectified within that period.
	3. Termination of this Subcontract will be without prejudice to the rights accruing to the Parties prior to the date of termination.
	4. If a Party is wholly or partially precluded from complying with its obligations under this Subcontract by failure to obtain and maintain an HREC Approval, the Party may by written notice to the other Party terminate the Subcontract, with immediate effect, without further liability for its failure to obtain and maintain such approvals.
	5. The Institution may terminate this Subcontract in the event, and on the same grounds that, the Head Agreement is, or may be, terminated.
	6. In the event of termination the Subcontractor must promptly initiate all appropriate action to initiate closeout of the Study in respect of those Study Participants for whom the Subcontractor is responsible, ensure they receive adequate medical care, and comply with any reasonable directions of the Institution or Reviewing HREC in relation to such matters.
	7. The following provisions survive termination of this Agreement, **clauses 1**, **3**, **5**, **7.1**, **7.2**, **7.3** **8**, **11**, **12**, **13.1**, **18.6** and **20**.
18. NOTICES
	1. A notice, consent, approval or other communication (each a notice) under this Subcontract must be:
		1. delivered to the Party’s address; or
		2. sent by pre-paid mail to the Party’s address;
		3. transmitted by facsimile to the Party’s address; or
		4. sent by email to the Party’s address.
	2. A notice given by a Party in accordance with this clause is treated as having been given and received:
		1. if delivered to a person’s address, on the day of delivery if a business day, otherwise on the next business day; or
		2. if sent by pre-paid mail, on the fifth business day after posting;
		3. if transmitted by facsimile to a person’s address and a correct and complete transmission report is received, on the day of transmission if a business day in the place of receipt, otherwise on the next business day at the place of receipt; or
		4. if sent by email before 5pm on a business day at the place of receipt, on the day it is sent and otherwise on the next business day at the place of receipt, and no bounce-back or delivery error message is received.
19. GENERAL
	1. The Subcontractor must provide evidence of compliance with its obligations under **clauses** 10 and **14** to the Institution or Sponsor on request.
	2. The Subcontractor shall not subcontract further its obligations under this Subcontract without the express written permission of the Institution.
	3. Each Party must do all things necessary or desirable to give effect to the provisions of this Subcontract including by signing all documents and performing all acts.
	4. This Subcontract:
		1. contains the entire agreement of the Parties; and
		2. supersedes all prior representations, conduct and agreements,
		3. with respect to its subject matter.
	5. Each Party is responsible for its own costs of entering into and performing this Subcontract.
	6. Any failure by a Party at any time to enforce a clause of the Subcontract, or any forbearance, delay or indulgence granted by a Party to another will not constitute a waiver of the Party’s rights.
	7. No provision of the Subcontract will be deemed to be waived unless that waiver is in writing and signed by the waiving Party.
	8. A waiver by a Party of a breach of any part of the Subcontract will not be a waiver of any subsequent breach of the same part nor a waiver of a breach of any other part.
	9. To the extent that any portion of this Subcontract is void or otherwise unenforceable then that portion will be severed and this Subcontract will be construed as if the severable portion had never existed.
	10. This Subcontract may be executed in two or more identical copy counterparts, each of which together will be deemed an original, but all of which together will constitute one and the same instrument.
	11. In the event that any signature executing this Subcontract or any part of this Subcontract 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 Subcontract upon execution by each individual party must be delivered to the remaining Parties.
	12. The laws in force in the State or Territory in which the Institution is located will apply to this Subcontract and each Party irrevocably submits to the exclusive jurisdiction of the Courts of that State or Territory, and Courts competent to hear appeals from those Courts.

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**EXECUTION**

Executed on the dates set out below:

|  |  |  |
| --- | --- | --- |
| **Signed for and on behalf of the [INSERT INSTITUTION] ABN [INSERT ABN]**  by its duly authorised officer: (name and title/position of person signing)this day of [year]in the presence of: (insert name and title/position of witness) |  |  (signature of authorised officer) (signature of witness) |
|  |  |  |
| **Signed for and on behalf of [INSERT SUBCONTRACTOR] ABN [INSERT ABN]** by its duly authorised officer: (print name and title/position of person signing)this day of [year]in the presence of (print name and title/position of witness) |  |  (signature of person signing) (signature of witness) |

**SCHEDULE 1 - PARTICULARS**

| **Item No.** | **Item** | **Detail** |
| --- | --- | --- |
| 1.
 | **Commencement Date** | **[INSERT DATE]**If no date is inserted, this is the date the last Party to sign this Subcontract signs this Subcontract. |
| 1.
 | **Completion Date** | **[INSERT DATE HREC APPROVAL LAPSES]** |
| 1.
 | **Study Title** | **[INSERT STUDY TITLE]** |
| 1.
 | **Institution** | **[INSERT ENTITY NAME]** ABN **[INSERT ABN]** located at **[INSERT PRINCIPAL ADDRESS OF BUSINESS]** |
| 1.
 | **Subcontractor** | **[INSERT ENTITY NAME]** ABN **[INSERT ABN]** located at **[INSERT PRINCIPAL ADDRESS OF BUSINESS]** |
| 1.
 | **Subcontractor Investigator** | **Subcontractor’s Investigator: [INSERT NAME AND CONTACT DETAILS OF SUBCONTRACTOR’S INVESTIGATOR]** |
| 1.
 | **Activities** | The following Activities specified in the Head Agreement and Protocol:* [*Specify Activities (including assessments) that all satellite sites will need to perform, for example:*
	+ *Pharmacy set-up*
	+ *Pharmacy annual administration*
	+ *Pharmacy storage*

*Pharmacy close-out*] |

**SCHEDULE 2 – PAYMENTS AND INVOICING**

**[INSERT PAYMENTS AND INVOICING TERMS AND CONDITIONS]**

**SCHEDULE 3 – HEAD AGREEMENT**

**[ATTACH HEAD AGREEMENT]**

**SCHEDULE 4 – INSURANCE ARRANGEMENTS**

| **Item** | **Description** | **Details** |
| --- | --- | --- |
| 1.
 | **Insurance Requirements** | **Public liability**Insured amount: <Institution to nominate amount as per jurisdictional policy> per claim and in the annual aggregate.**Professional indemnity**Insured amount: <Institution to nominate amount as per jurisdictional policy> per claim and in the annual aggregate. |
|  | **Certificate of Insurance** | The Certificate of Insurance must have the following details:* Insurance provider
* Insured Entity
* Additional Insured (if any)
* Protocol/ CTN number
* Limits of Liability in AUD/ Per occurrence amount and Annual Aggregate
* Excess/ deductible/ Self-insured risk
 |