

# CLINICAL TRIAL RESEARCH AGREEMENT SUBCONTRACT

## FOR STUDIES CONDUCTED UNDER A TELETRIAL MODEL

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

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

**AND:** each **Subcontractor** so described in **Schedule 1** (each a '**Subcontractor**')

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### RECITALS

- A. The Institution is an HHS or a facility that is part of an HHS that is bound by the *Hospital and Health Boards Act 2011* (Qld).
- B. A principle, set out in section 13(1)(i), guiding the achievement of the objects of the *Hospital and Health Boards Act 2011* (Qld) is that opportunities for research and development relevant to the delivery of public sector health services should be promoted.
- C. The Institution has been engaged by the Sponsor to perform the Study under the Head Agreement.
- D. The Institution seeks for each Subcontractor to perform activities on its behalf for the Study.
- E. The Parties agree to perform their respective activities relating to the Study as set out in this Subcontract.

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### OPERATIVE PROVISIONS

#### 1. RECITALS

The Parties acknowledge the truth and accuracy of the Recitals in every particular.

#### 2. DEFINITIONS AND INTERPRETATION

##### 2.1. 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 6** of **Schedule 1** both common to all Subcontractors and specific to each relevant Subcontractor as specified.

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

**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**.

**HHS or Hospital and Health Service** means a Hospital and Health Service established under section 17 of the *Hospital and Health Boards Act 2011* (Qld).

**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 each Subcontractor.

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

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

**Subcontractor** means each organisation so described in **Item 5** of **Schedule 1** on condition it executes this Subcontract.

**Subcontractor's Confidential Information** means, in respect of a Subcontractor, information in relation to the Subcontractor's organisation, business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors, including information that:

- (a) is by its nature confidential;
  - (b) is designated as confidential by the Subcontractor;
  - (c) the recipient Party or a recipient party to the Head Agreement knows or ought reasonably to know is confidential;
- but does not include information that:
- (d) is Personal Information;
  - (e) was already in the possession of the recipient Party or a recipient party to the Head Agreement and not subject to an obligation of confidentiality;
  - (f) is lawfully received from a third party or independently developed by the recipient Party or a recipient party to the Head Agreement;
  - (g) is public knowledge other than through a breach of an obligation of confidentiality owed by the recipient Party or a recipient party to the Head Agreement; or
  - (h) the Parties agree is not confidential.

## 2.2. Interpretation

- (a) In this Subcontract, the index and clause headings have been inserted for ease of reference only and are not intended to affect the meaning or interpretation of this Subcontract.
- (b) The following rules apply in interpreting this Subcontract, unless the context otherwise requires:

- (i) words importing a gender include the other gender;
- (ii) words in the singular include the plural and vice versa;
- (iii) all dollar amounts refer to Australian currency;
- (iv) a reference to any legislation includes any subordinate legislation made under it and any legislation amending, consolidating or replacing it;
- (v) a reference to an entity or person includes an individual, corporation, partnership or other legal entity;
- (vi) a party includes its executors, administrators, liquidators, successors and permitted assigns;
- (vii) "consent" means prior written consent;
- (viii) "in writing" means either by letter, email or facsimile;
- (ix) a reference to a clause, attachment or annexure is a reference to a clause, attachment or annexure to this Subcontract;
- (x) if a day on which an act is to be done is a Saturday, Sunday or public holiday in the place where the act is to be done, the act may be done on the next Business Day in that place, unless the Parties agree otherwise;
- (xi) if any expression is defined, other grammatical forms of that expression will have corresponding meanings, unless the context otherwise requires;
- (xii) a reference to a clause is a reference to all of its sub-clauses;
- (xiii) a document or agreement or a provision of a document or agreement, is a reference to that document, agreement or provision as amended, supplemented, replaced or novated.

### **3. TERM**

- 3.1. This Subcontract commences on the Commencement Date and will continue until the Completion Date unless terminated earlier in accordance with this Subcontract.
- 3.2. The Parties may extend the Completion Date by mutual written agreement.
- 3.3. If the Commencement 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.

### **4. NATURE OF THIS SUBCONTRACT**

This agreement 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 each Subcontractor as if they were the Institution's acts and omissions in accordance the Head Agreement.

## **5. SUBCONTRACTED ACTIVITIES**

Each Subcontractor will perform the Activities in accordance with:

- (a) the Protocol;
- (b) the terms of the Head Agreement applicable to the Institution which apply to those Activities;
- (c) the principles of good scientific and clinical research practices;
- (d) all applicable local, State and Federal laws, legislation, regulations, rules and by-laws; and
- (e) the TGA approval for the Study, the HREC Approval and all relevant Reviewing HREC directions issued from time to time.

## **6. INVESTIGATIONAL PRODUCT**

Where a Subcontractor's pharmacy will handle and dispense medicine(s) constituting an Investigational Product, it will:

- (a) use the medicine(s) solely for the Study and not for any other purpose; and
- (b) 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, in accordance with applicable laws, regulations and the Institution's policies and procedures.

## **7. MEETINGS**

Each Subcontractor's investigator for the Study will meet with each other Party's 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.

## **8. MONITORING VISITS AND REGULATORY AUTHORITIES**

- 8.1. Subject to clause 12, each Subcontractor will allow regular monitoring visits in accordance with the same terms as those applicable to the Institution under the Head Agreement.
- 8.2. If a 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.
- 8.3. Each 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 Sponsor unless such rectification is due to the default of the Subcontractor or its Personnel.
- 8.4. Each Subcontractor:
  - (a) warrants that it is not and has not been debarred or disqualified from participating in clinical research by any United States Regulatory Authority or by any other Regulatory Authority,

and that it will not involve any person or organisation in connection with the Study that is or has been so debarred or disqualified; and

- (b) 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.

## **9. RECORDS AND INTELLECTUAL PROPERTY**

9.1. Each Subcontractor must:

- (a) 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;
- (b) ensure that no Study Materials are destroyed before the expiration of the time period specified in the Head Agreement without the written approval of the Institution; and
- (c) 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.

9.2. The Institution grants to each Subcontractor and its Personnel the same rights to use the Background IP and Study Materials granted to the Institution under the Head Agreement on the same conditions for the purposes of the Study.

9.3. Each 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 specified in the Head Agreement.

9.4. All Intellectual Property in the Study Materials created by each Subcontractor will vest automatically upon its creation in the Sponsor on the same terms as those applicable to the Institution under the Head Agreement.

## **10. PAYMENTS AND INVOICING**

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.

## **11. PERSONNEL**

11.1. Each Subcontractor warrants that each person engaged by it to perform any part of the Activities:

- (a) is competent;
- (b) has the necessary and appropriate qualifications, licenses, admissions, memberships, credentials, authorisations and skills to ensure they are both qualified and able to perform the relevant activities; and,
- (c) 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 Act 2009* (Qld), at all times the relevant health professional meets their registration and accreditation requirements under that Act.

11.2. Each 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.

11.3. Each Subcontractor will give written notice to the Institution promptly upon becoming aware that it no longer complies with the warranties and assurances provided in this clause.

## **12. CONFIDENTIALITY**

12.1. Each Subcontractor must not use '*confidential information*' as defined in Part 7 of the *Hospital and Health Boards Act 2011* (Qld) other than in accordance with that Act.

12.2. Subject to clause 12.3, each 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.

12.3. Each Subcontractor may use or disclose the Institution's or Sponsor's Confidential Information in any of the circumstances applicable to the Institution set out in the Head Agreement on the same terms as those applicable to the Institution under the Head Agreement:

12.4. Where Confidential Information is disclosed in accordance with clause 12.3, the Confidential Information must only be used in connection with the legitimate purposes of the Subcontractor, and only disclosed to those who have a need to know it for such purposes and are obligated to keep the information confidential.

12.5. The Institution or Sponsor may disclose each Subcontractor's Confidential Information:

(a) on a need to know and confidential basis to its Affiliates and for the purpose of obtaining legal advice; or

(b) if required by law, with notice as soon as reasonably practical to the Subcontractor, and subject to the 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.

12.6. Each Party is responsible for ensuring that its Personnel are aware of the obligations in respect of Confidential Information, and are bound in similar terms to keep such information confidential.

12.7. Information will not be Confidential Information where it satisfies the requirements of the Head Agreement for the same.

## **13. PRIVACY**

13.1. Each 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.

- 13.2. Each 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.
- 13.3. Each Subcontractor agrees that the Sponsor 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's business partners and vendors working with Sponsor on matters related to the Study solely for the following purposes:
- (a) compliance with laws and regulations regarding possible financial conflicts of interest;
  - (b) assessment of Personnel qualifications to conduct the Study;
  - (c) Study quality control and management; or
  - (d) 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.
- 13.4. Where required, each Subcontractor will 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 section.
- 13.5. Sponsor must comply with the Relevant Privacy Laws applicable to it regarding its collection, storage, use and disclosure of Subcontractor Personnel Information.

#### **14. PROMOTIONAL MATERIAL AND PUBLICATION**

- 14.1. Subject to clause 14.2, each Party will not use the name or names of other Parties, the Sponsor, or their Personnel in any advertising or sales promotional material or in any Publication without prior written permission.
- 14.2. Sponsor may disclose that each Subcontractor is involved in the Study, the type of services performed by each Subcontractor, and the existence and terms of this Subcontract only where required for compliance with applicable laws and regulations.

#### **15. SECURITY**

- 15.1. Each Subcontractor warrants that:
- (a) 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
  - (b) 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.

## **16. ANTI-BRIBERY / ANTI-CORRUPTION**

Each 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, 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**

- 17.1. A Party may terminate this Subcontract for breach of this Subcontract provided that it gives thirty (30) days prior notice of the breach to the other Party and that the breach is not rectified within that period.
- 17.2. Termination of this Subcontract will be without prejudice to the rights accruing to the Parties prior to the date of termination.
- 17.3. 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 Parties terminate the Subcontract, with immediate effect, without further liability for its failure to obtain and maintain such approvals.
- 17.4. The Institution may terminate this Subcontract in the event, and on the same grounds that, the Head Agreement is terminated.
- 17.5. If a Party terminates this Subcontract:
- (c) the Subcontract is terminated as between the terminating Party and the other Parties; and
  - (d) remains in operation as between the other Parties other than the terminating Party.
- 17.6. The following provisions survive termination of this Subcontract, clauses 2, 4, 6, 8, 9, 12, 13, 14, 18.

## **18. GENERAL**

- 18.1. Each Subcontractor shall not subcontract further their obligations under this Subcontract without the express written permission of the Institution.
- 18.2. 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.
- 18.3. This Subcontract:
- (a) contains the entire agreement of the Parties; and
  - (b) supersedes all prior representations, conduct and agreements,

with respect to its subject matter.

- 18.4. Each Party is responsible for its own costs of entering into and performing this Subcontract.
- 18.5. 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.
- 18.6. No provision of the Subcontract will be deemed to be waived unless that waiver is in writing and signed by the waiving Party.
- 18.7. 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.
- 18.8. 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.
- 18.9. 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.
- 18.10. 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.
- 18.11. The laws of the State of Queensland, Australia, apply to this Subcontract and each Party irrevocably submits to the exclusive jurisdiction of the Courts of Queensland, Australia, and Courts competent to hear appeals from those Courts.

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**EXECUTION**

Executed as a deed of agreement on the dates below:

**Signed, sealed and delivered for and on behalf of the [INSERT INSTITUTION] ABN [INSERT ABN] by its duly authorised officer:**

.....  
(name and title/position of person signing)

.....  
(signature of authorised officer)

this ..... day of  
..... 2018

in the presence of:

.....  
(insert name and title/position of witness)

.....  
(signature of witness)

**Signed, sealed and delivered for and on behalf of [INSERT SUBCONTRACTOR] ABN [INSERT ABN] by its duly authorised officer:**

.....  
(print name and title/position of person signing)

.....  
(signature of person signing)

this ..... day of  
..... 2018

in the presence of

.....  
(print name and title/position of witness)

.....  
(signature of witness)

**[Replicate the above execution block as required for the number of Subcontractors]**



## SCHEDULE 1 - PARTICULARS

Item No.	Item	Detail						
1.	Commencement Date	<p><b>[INSERT DATE]</b></p> <p>If no date is inserted, this is the date the last Party to sign this Agreement signed this Agreement.</p>						
2.	Completion Date	<b>[INSERT DATE HREC APPROVAL LAPSES]</b>						
3.	Study Title	<b>[INSERT STUDY TITLE]</b>						
4.	Institution	<b>[INSERT ENTITY NAME]</b> ABN <b>[INSERT ABN]</b> located at <b>[INSERT PRINCIPAL ADDRESS OF BUSINESS]</b>						
5.	Subcontractor/s	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Ref.</th> <th style="text-align: center;">Subcontractor Details</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">A.</td> <td><b>[INSERT ENTITY NAME]</b> ABN <b>[INSERT ABN]</b> located at <b>[INSERT PRINCIPAL ADDRESS OF BUSINESS]</b></td> </tr> <tr> <td style="text-align: center;">B.</td> <td><i>[Replicate the above as required for the number of Subcontractors]</i></td> </tr> </tbody> </table>	Ref.	Subcontractor Details	A.	<b>[INSERT ENTITY NAME]</b> ABN <b>[INSERT ABN]</b> located at <b>[INSERT PRINCIPAL ADDRESS OF BUSINESS]</b>	B.	<i>[Replicate the above as required for the number of Subcontractors]</i>
Ref.	Subcontractor Details							
A.	<b>[INSERT ENTITY NAME]</b> ABN <b>[INSERT ABN]</b> located at <b>[INSERT PRINCIPAL ADDRESS OF BUSINESS]</b>							
B.	<i>[Replicate the above as required for the number of Subcontractors]</i>							
6.	Activities	<p style="text-align: center;"><b>Activities common to all Subcontractors</b></p> <p>The following Activities specified in the Head Agreement and Protocol that are common to all Subcontractor/s specified in Item 5 of this Schedule 1:</p> <ul style="list-style-type: none"> <li>• <b>[Specify Activities (including assessments) that all satellite sites will need to perform, for example:</b> <ul style="list-style-type: none"> <li>○ <b>Pharmacy set-up</b></li> <li>○ <b>Pharmacy annual administration</b></li> <li>○ <b>Pharmacy storage</b></li> <li>○ <b>Pharmacy close-out]</b></li> </ul> </li> </ul> <p style="text-align: center;"><b>Activities relevant to specific Subcontractors</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td style="text-align: center;">A.</td> <td><b>[Corresponding with the Ref. letter of each Subcontractor listed in Item 5 above, specify exceptions or additions, if any, to the above list of common activities that apply to the Subcontractor (insert 'NIL' if none for a Subcontractor)]</b></td> </tr> </tbody> </table>	A.	<b>[Corresponding with the Ref. letter of each Subcontractor listed in Item 5 above, specify exceptions or additions, if any, to the above list of common activities that apply to the Subcontractor (insert 'NIL' if none for a Subcontractor)]</b>				
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## SCHEDULE 2 – PAYMENTS AND INVOICING

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

## SCHEDULE 3 – HEAD AGREEMENT

**[ATTACH HEAD AGREEMENT]**

