**Research Funding Agreement**

(The body of this Standard Form Agreement should not be amended. Any proposed changes to this Agreement must be incorporated into **Schedule 4** by way of Special Conditions)

# Details of the Parties

|  |  |
| --- | --- |
| **Name of Institution:** | **(name of Health Service Provider), a body corporate established under section 32 of the Health Services Act 2016** |
| Address: |  |
| ABN: |  |
| Contact for Notices: |  |
| Fax for Notices: |  |
| Email for Notices: |  |
| Phone Number: |  |
|  |  |
| **Organisation:** |  |
| Address: |  |
| ABN: |  |
| Contact for Notices: |  |
| Fax for Notices: |  |
| Phone Number: |  |

# THIS AGREEMENT IS MADE BETWEEN THE ORGANISATION AND THE INSTITUTION

PURPOSE OF THE AGREEMENT

According to this Agreement:

1. The Institution, through the Principal Investigator, is responsible for the initiation, management and conduct of the Research at the Research Site(s) which is/are under the control of the Institution.
2. The Organisation has agreed to contribute to the funding of the Research.
3. The Research will be conducted on the terms and conditions set out below.

OPERATIVE PROVISIONS

# INTERPRETATION

## In this Agreement:

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

**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 Therapeutic Goods Administration, as amended from time to time.

**GST** means the Goods and Services Tax payable under a GST Law.

**GST Law** means the same as in *A New Tax System (Goods and Services Tax) Act 1999 (Cth)* as amended from time to time, and any regulations made pursuant to that Act.

**Institution** means the body so described on the first page of this Agreement.

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

### 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 as recognised by the law in force in Western Australia; and

### any application or right to apply for registration of any of those rights.

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

**Organisation** means the corporate entity so described on the first page of this Agreement.

**Principal Investigator** is the person responsible for the conduct of the Research at the Research Site as described in **Schedule 1.**

**Protocol** means the document which describes the objective(s), design, methodology, statistical considerations and organisation of the Research, as such document may be amended from time to time and most recently approved by the Responsible HREC.

**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 Research 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 Research at the Research Site and includes any overseas regulatory authorities who may require to audit any part of the Research or Research Materials.

**Research** means the investigation/s to be conducted in accordance with the Protocol/s.

**Responsible HREC** means the Human Research Ethics Committee reviewing the Research on behalf of the Institution as described in **Schedule 1**.

**Research Site** means the location(s) under the control of the Institution where the Research is actually conducted.

## Except where the context otherwise requires:

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

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

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

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

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

### 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; and

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

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

# RESEARCH

## The Institution must comply with, and conduct the Research in accordance with the following, in the following order of precedence:

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

### any condition of the Responsible HREC; and

### the Protocol;

### and additionally as applicable:

### the NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007) or replacement, and any other relevant NHMRC publication or guideline that relates or may relate to clinical trials;

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

### the GCP Guideline.

# PRINCIPAL INVESTIGATOR

## **Role of Principal Investigator**

The Institution has authorised the Principal Investigator as the person responsible on a day-to-day basis for the conduct of the Research. The Principal Investigator does not have authority on behalf of the Institution to amend this Agreement or the Protocol.

## **Obligations and responsibilities**

The Institution is responsible for ensuring that the Principal Investigator:

### confirms written approval has been obtained to conduct the Research from the Responsible HREC and the Institution prior to Research initiation. Written documentation of approval by the Responsible HREC and the Institution must be provided to the Organisation;

### conducts the Research according to the Protocol without changes except as approved in accordance with **clause 3.2(3)**;

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

### provides regular written progress reports to the Organisation in relation to the Research if requested by the Organisation;

# INSTITUTION

## **Obligations and responsibilities**

### If the Principal Investigator leaves the Institution or otherwise ceases to be available, the Institution must consult with the Organisation and use reasonable endeavours to nominate as soon as practicable a replacement reasonably acceptable to both Parties. If the parties cannot agree on a replacement, either party may terminate this Agreement in accordance with **clause 9.3**.

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

### The Institution will make available adequate facilities, equipment and any other resource of the Institution reasonably required to safely follow the Protocol, provided that any amendments to the Protocol which take place after the execution of this Agreement and requiring any additional use of facilities, equipment, staff or resources, have been approved in writing by the Responsible HREC.

### The Institution will have an adequate number of appropriately qualified Personnel for the foreseen duration of the Research and ensure that such Personnel are adequately informed about the Protocol, Investigational Product(s), and their Research related duties and functions.

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

# PAYMENTS

## In consideration of the Institution conducting the Research, the Organisation will pay to the Institution as nominated in **Schedule 2** in the manner and on the basis of the prices and at the times set out in **Schedule 2**. The prices set out in **Schedule 2** do not include GST. At the time of payment, the Organisation must pay to the Institution any amount of GST that the Institution is required to pay in addition to the prices set out in **Schedule 2**, and in accordance with GST Law.

## Payments will be made by the Organisation upon either receipt of a valid tax invoice or a “Recipient Created Tax Invoice” issued by the Organisation, if applicable.

## the Organisation and the Institution warrant that they are registered under GST Law. Tax invoices must identify supplies for which GST is payable.

# PUBLICATIONS

## The Institution, Principal Investigator and other investigators (“Discloser”) involved in the Research have the right to Publish the methods, results of, and conclusions from, the Research.

## In any Publication referred to in **clause 6.1** the Discloser will acknowledge the contribution of the Organisation.

# RESEARCH RESULTS AND INTELLECTUAL PROPERTY

## All Intellectual Property created in the course of the Research belongs to the Institution.

# LIABILITY AND INSURANCE

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

## Each party 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 Research or performing its obligations under this Agreement.

## The Institution satisfies the requirements of clause 8.2 if it is entitled to an indemnity under a program or scheme of insurance or indemnity that is arranged by a State or Territory of the Commonwealth of Australia.

# TERM AND TERMINATION

## This Agreement commences from the date specified on the first page of this Agreement, or if such date is not included on the date this Agreement is last signed by either the Organisation or Institution. In the ordinary course of events this Agreement terminates when the Organisation makes its final payment to the Institution.

## The Organisation may terminate this Agreement with 30 days prior written notice or such shorter time period as is reasonably required in the circumstances if the Institution assigns this Agreement to a person considered unsuitable to perform the Agreement as set out in **clause 14.1**.

## Either party may terminate the Agreement by giving 30 days prior written notice to the other in the circumstances described in **clause 4.1(1)**.

# APPLICABLE LAW

## This Agreement is governed by the laws of Western Australia and the Commonwealth of Australia. Each party submits to the exclusive jurisdiction of courts exercising jurisdiction in Western Australia and the Commonwealth of Australia in connection with all matters concerning this Agreement.

# NOTICES

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

### delivered to the party’s address;

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

### transmitted by facsimile to the party’s address.

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

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

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

### if transmitted by facsimile to a person’s address and a correct and complete transmission report is received, on the day of transmission if a business day, otherwise on the next business day.

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

# WAIVER

## No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the party waiving the right. A waiver by any party in respect of any breach of a condition or provision of this Agreement will not be deemed to be a waiver in respect of any other breach.

## Failure or delay by any party to enforce any provision of this Agreement will not be deemed to be a waiver by that party of any right in respect of any other such breach.

# VARIATIONS

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

# ASSIGNMENT

## The Institution may assign this Agreement to any entity which assumes control of it but must givethe Organisation notice in writing of any such assignment and obtain from the relevant assignee a written undertaking in favour of the Organisation to be bound by the terms of this Agreement.

## The Organisation may assign the benefit of this Agreement provided it obtains from the relevant assignee a written undertaking in favour of the Institution to be bound by the terms of this Agreement.

# ENTIRE AGREEMENT

This Agreement (including all documents referred to in this Agreement) constitutes the entire agreement between the parties and supersedes all prior representations, agreements, statements and understandings, whether verbal or in writing.

# RELATIONSHIP OF THE PARTIES

Nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the parties and no party will hold itself out as an agent for another.

In witness hereof, the parties have caused this Agreement to be executed as of respective dates written below.

Signed on behalf of the **Organisation**

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

Signed on behalf of the **INSTITUTION**

by

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

for and on behalf of [**name of** **Health Service Provider]** in accordance with section 41 of the *Health Services Act* 2016

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

Acknowledged by the **Principal Investigator**

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

**Schedule 1**

# Key Information

(to be inserted by Institution)

|  |  |
| --- | --- |
| Research Name: |  |
| Research Site/s: |  |
| Protocol Number: |  |
|  |  |
| Principal Investigator  Name: |  |
| Address: |  |
|  | State: P/code: |
|  |  |
|  | |
| Responsible HREC: |  |
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**Schedule 2**

**Payments**

**Schedule 3**

**Research Protocol Identification**

Full Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Version Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_\_

List of Key attachments:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Schedule 4**

Special Conditions

**Amendment to Clauses in the Body of the Agreement**