**Research Collaboration Agreement**

**For an Investigator Initiated Study**

This Agreement is based on the Alfred Health & Melbourne Health Research Collaboration Agreement and the Victorian Managed Insurance Authority (VMIA) Clinical Trial Research Agreement for an Investigator Initiated Study.

The body of this Agreement should not be amended. Any proposed changes to this Agreement must be incorporated in Schedule 3 by way of Special Conditions.

**Details of the Parties**

|  |
| --- |
| **Organisation:**Address:      ABN:      Contact for Notices:           Fax for Notices:      Phone Number:       |
| **Institution:** Address:      ABN:      Contact for Notices:      Fax for Notices:      Phone Number:       |
| **Study Name:** Protocol Number (or HREC Number):      Date of Agreement: Date of last Party to sign  |

This agreement is made between the Institution and the Organisation

**RECITAL**

According to this Agreement:

1. The Organisation has initiated the Study and has prepared and owns the Protocol. The Organisation may also agree to support the Study in other ways - for example, by providing funding for the Study.
2. The Institution, through the Principal Investigator, is responsible for the conduct of the Study at the Study Site(s) which is/are under the control of the Institution.
3. The Parties wish to conduct research and development with a view to achieving agreed research objectives through a Study on the terms and conditions set out in this Agreement.

**IT IS AGREED AS FOLLOWS:**

1. DEFINITIONS
	1. In this Agreement:

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

***Background IP***means, in relation to a Party, the Intellectual Property in all information and materials disclosed or provided by the Party (whether before or after the date this Agreement is fully executed) to another Party for the purpose of the Study, but does not include Project IP.

***Commercialisation*** in relation to Intellectual Property, means to manufacture, sell, hire or otherwise exploit a product or process, or to provide a service, incorporating that Intellectual Property, or to license or assign Intellectual Property to any third party to do any of those things.

***Confidential* *Information*** means any information which is disclosed or made available in connection with this Agreement and that:

* + 1. the Parties agree in writing is confidential; or
		2. is by its nature, confidential;

but does not include information which:

* + 1. is or becomes part of the public domain, unless it came into the public domain by a breach of confidentiality;
		2. is obtained lawfully from a third party without any breach of confidentiality;
		3. is already known by the recipient Party (as shown by its written record) before the date of disclosure to it;
		4. is independently developed by an employee of the recipient Party who has no knowledge of the disclosure under this Agreement;
		5. is required to be disclosed in compliance with applicable law, government regulation or a court order;
		6. is disclosed for the purposes of monitoring by the relevant Ethics Committee;
		7. is disclosed for the purposes of legal advice or to the Party’s insurer; or
		8. is legally directed to be disclosed to Parliament (including committees of it), and Ministers of the Crown.

*Funding* means the funding to be provided by the Organisation to the Institution in the amount and in the manner set out in Schedule 2. The amounts set out in Schedule 2 do not include GST.

*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.

***Health Information*** means health information as defined in any applicable Privacy Laws.

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

***Intellectual Property*** means statutory and other proprietary rights in respect of trademarks, patents, circuit layouts, copyright, confidential information and all other rights with respect to intellectual property as defined in Article 2 of the *Convention establishing the World Intellectual Property Organisation* of July 1967.

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

***Party*** means a party to this Agreement and **Parties** means both Parties to this Agreement***.***

***Personal Information*** means personal information as defined in any applicable Privacy Laws.

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

***Privacy Laws*** means Commonwealth and/or State and/or Territory legislation, principles, codes and guidelines in relation to the collection, use, storage and security or disclosure of any Personal Information and/or Health Information which applies in the jurisdiction in which the Study Site is located.

***Project IP*** means any Intellectual Property created, invented or discovered in carrying out the Study but does not include Background IP or copyright in a Student’s thesis or other material produced by him/her for the purpose of assessment towards his/her degree.

***Protocol*** means the document identified in Schedule 1 which describes the objective(s), design, methodology, statistical considerations and organisation of the Study, as amended from time to time and most recently approved by the Responsible HREC.

***Representative*** has the meaning set out in clause 3.1.

***Responsible HREC*** means the Human Research Ethics Committee reviewing the Study on behalf of the Institution as described in Schedule 1.
***Schedule*** means a schedule to this Agreement.

***Study*** means the research collaboration to be conducted in accordance with the Protocol.

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

***Term*** has the meaning set out in clause 7.1.

* 1. In this Agreement:
		1. a reference to a Party includes a reference to that Party’s administrator, successors and permitted assigns;
		2. headings are for guidance only, and do not affect interpretation;
		3. a reference to any statute is a reference to that statute, as amended and in force from time to time;
		4. a reference to a Party means each Party to this Agreement, its officers, employees, sub-contractors, agents and persons for which it is vicariously liable, and its respective successors and permitted assigns.
	2. The following items have the following descending order of precedence to the extent of any conflict or inconsistency between them:
		1. the terms and conditions of the clauses of this Agreement;
		2. the Schedules;
1. RESEARCH PROJECT
	1. Each Party agrees to carry out its obligations under this Agreement and conduct the Study in accordance with:
		1. the Protocol;
		2. any condition of the Responsible HREC;
		3. any applicable laws; and
		4. the *National Statement on Ethical Conduct in Human Research 2007 and The Australian Code for Responsible Conduct of Research 2007* (as varied or replaced by the National Health & Medical Research Council, the Australian Research Council and Universities Australia).
	2. Each Party must:
		1. bear its own costs under this Agreement or, if Funding is provided by the Organisation, as specified in clause 9 and Schedule 2;
		2. obtain and comply with all required authorisations from government agencies and ethics committees which are required for the Study; and
		3. not knowingly infringe, and use its best endeavours not to infringe, the Intellectual Property rights of any person in carrying out the Study.
2. REPRESENTATIVES AND NOTICES
	1. Each Party nominates as its representative for this Agreement the person set out on the first page of this Agreement under ‘Contact for Notices’ (“**Representative**”).
	2. Any communication under this Agreement must be in writing and sent to the recipient Party’s Representative.
3. STUDY RESULTS AND PROJECT IP
	1. The data and results of the Study and the Protocol are the property of the Organisation unless otherwise agreed in writing between the Parties.
	2. Unless otherwise specified in Schedule 3, the Parties agree that all rights, title and interest in the Project IP will be owned solely by the Party, or jointly by the Parties, that contribute to its development or creation and, in the case of jointly owned Project IP, the Parties will own the Project IP in shares proportionate to their respective intellectual contributions to the development or creation of that Intellectual Property.
	3. In the case of jointly owned Project IP, neither Party may:
		1. grant a licence of its share of any Project IP; or
		2. assign its share of the Project IP,

without the written consent of the other Party, which will not be unreasonably withheld.

* 1. The Parties agree that copyright in a student thesis will be owned by the student but the Party responsible for the student will ensure that the student enters into a written agreement which is consistent with this Agreement and the terms of this clause 4 before the student commences any Study activities.
	2. Each Party agrees to promptly provide written notice to the other Party of any Project IP that may have potential commercial value on becoming aware of any such Project IP. The Parties will consult and decide what (if any) measures should be taken to protect the Project IP and negotiate in good faith and using all best endeavours to agree the terms of any program of commercialisation arising from the Project IP so as to fairly share in any commercial return associated with the Study and the Project IP.
	3. Having regard to any requirements to protect potentially commercially valuable Project IP, each Party grants to each other Party a non-exclusive, non-transferable, perpetual, royalty free, worldwide licence to use the Project IP it owns for:
		1. non-commercial research, education and training purposes; and
		2. publication purposes (subject to clause 6 of this Agreement).
	4. The Parties are committed to appropriate recognition of contributions to invention and exploitation of Intellectual Property for the benefit of the Australian community.
1. BACKGROUND IP
	1. The Parties agree that the ownership of Background IP is not affected by this Agreement and that all Background IP remains the property of the Party that makes it available for the purpose of carrying out the Study.
	2. No representations or warranties are made or given in relation to Background IP, however each Party making available Background IP acknowledges that to the best of its knowledge, such Background IP when used in accordance with this Agreement will not infringe any third party Intellectual Property rights.
	3. Each Party grants to the other Party for the Term a royalty free, non-exclusive licence to use its Background IP to the extent necessary to carry out the Study.
2. PUBLICATION
	1. A Party may publish the results of the Study subject to this clause 6.
	2. At least 28 days prior to any publication, the publishing Party must provide a copy of the proposed publication to the other Party.
	3. The other Party may provide comments and/or reasonable amendments to the publication to protect its Confidential Information and/or Intellectual Property provided they are given to the publishing Party in writing no later than 14 days before the publication is proposed. If no such comments or amendments are provided within those 14 days, the publishing Party can make the publication.
	4. All publications will recognise the contribution by the Parties to the Study.
3. TERM AND TERMINATION
	1. This Agreement commences on 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 a Party and expires on completion of the Study unless terminated earlier in accordance with this clause 7 (“**Term**”).
	2. Either Party may terminate the Agreement by giving 28 days prior written notice to the other.
	3. In the event of termination, the Parties must promptly initiate all appropriate action to close the Study and, subject to any applicable retention requirements imposed by law, return to the other Party (or destroy if requested, and provide evidence of such destruction) any materials received from a Party before termination of this Agreement. Where Funding has been provided by the Organisation, the Institution must reimburse any Funding that has not yet been expended as at the date of termination. The Parties must also return any Confidential Information within 14 days of the date of termination.
4. LIABILITY AND INSURANCE
	1. Each Party is liable for its acts and omissions in relation to the conduct of the Study.
	2. Each Party must maintain such insurances as are necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study or performing its obligations under this Agreement.
	3. A Party satisfies the requirements of clause 8.2 if it is entitled to indemnity under a program or scheme of insurance or indemnity that is arranged by a department or agency of a State or Territory of the Commonwealth of Australia.
5. FUNDING
	1. Where the Organisation is providing Funding to the Institution, the Organisation must provide to the Institution any amount of GST that the Institution is required to pay in addition to the Funding, and in accordance with GST Law.
	2. Payment of the Funding must be made by the Organisation upon either receipt of a valid tax invoice or by way of a “Recipient Created Tax Invoice” issued by the Organisation.
	3. The Organisation and the Institution warrant that they are registered under GST Law. Tax invoices must identify supplies for which GST is payable.
	4. In the event of early termination of this Agreement, the Institution must reimburse any amount of funding provided by the Organisation that has not been expended by the Institution up until the date of termination.
6. CONFIDENTIALITY AND PRIVACY
	1. Subject to clause 10.2, where a Party (“**Disclosing Party**”)provides Confidential Information to the other Party (“**Recipient**”) the Recipient must not:
		1. use the Confidential Information except to the extent such use is necessary for the performance of the Study; and
		2. disclose the Confidential Information to any third party,

except with the prior written consent of the Disclosing Party.

* 1. The Recipient may disclose Confidential Information of the Disclosing Party to such of its directors, officers, employees and professional advisers as is necessary for the purposes of the Study provided that the person to whom the Recipient discloses the Confidential Information is subject to contractual or other duties of confidentiality to the Recipient at least equivalent to the duties of confidentiality imposed upon the Recipient under this Agreement.
	2. The Parties must ensure that any Personal Information or Health Information arising from the Study is collected, stored, used and disclosed in accordance with applicable Privacy Laws.
1. DISPUTES
	1. A Party may not commence legal proceedings against the other in respect of a dispute arising in relation to this Agreement (except for urgent interlocutory relief) unless the Parties have complied with this clause and that Party has first notified the other Party in writing of the dispute and has used all reasonable endeavours to resolve the dispute with the other Party including referring it to senior representatives within 28 days of the giving of that notice (“**Initial Period**”).
	2. If the dispute is not resolved within the Initial Period, then the dispute shall be referred within a further 28 days to the Australian Commercial Disputes Centre for mediation or any other agreed venue which conducts mediation. The Parties will by agreement appoint a mediator to mediate the dispute in this forum. If the Parties cannot agree to a mediator, then the mediator will be nominated by the then current President of the Law Society of the State or Territory in which the Institution is located. Any documents produced for the mediation are to be kept confidential and cannot be used except for the purpose of settling the dispute.
	3. Each Party must bear its own costs of resolving a dispute under this clause, and unless the Parties otherwise agree, the Parties to the dispute must bear equally the costs of the mediator.
	4. In the event that the dispute is not settled at mediation within 28 days (or such other period as the Parties agree in writing) after the appointment of the mediator, or if no mediator is appointed, then within 28 days of the referral of the dispute to mediation, then the Parties are free to pursue any other procedures available at law for the resolution of the dispute.
2. GENERAL
	1. This Agreement constitutes the entire agreement and understanding between the Parties with respectto the subject matter of this Agreement.
	2. The body of this Agreement (page 2 to 9 including the execution clause) is intended to be in standard form, a copy of which is located at www.nh.org.au. The Parties warrant that the body of this Agreement is in standard form. Any amendment must be incorporated in Schedule 3 ‘Special Conditions’.
	3. Any variation of any term and condition of this Agreement or the Study must be made in writing and executed by all Parties.
	4. A Party must not assign the rights and obligations arising under this Agreement without the prior written consent of the other Party.
	5. The Parties are independent contracting Parties and nothing in this Agreement makes any Party the employee, partner, agent, or legal representative of any other for any purpose whatsoever, nor does it grant either Party any authority to assume or to create any obligation on behalf of or in the name of any other.
	6. Any provision of this Agreement that is invalid or unenforceable will be deemed deleted, but only to the extent necessary and remaining provisions remain in full force and effect.
	7. This Agreement does not preclude any Party engaging in research or other activities similar to the Study or its subject matter.
	8. This Agreement is governed by the laws of the State of Victoria and each Party submits to the exclusive jurisdiction of the courts of that State.
	9. This Agreement may be signed in any number of counterparts which together will constitute one agreement.
	10. Each Party may communicate its execution of this Agreement by successfully transmitting an executed copy of this Agreement by email to the other Party.
	11. This clause 12 and clauses 1, 4, 6, 8 and 10 will survive termination of this Agreement.

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**

Signed: …………………………………. Name: …………………………………..

Position: ………………………………… Date: …………………………………….

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

Acknowledged by the **Principal Investigator**

Signed: ………………………………….…. Name: …………………………………..

Position: …………………………………… Date: ………….………………………….

1. Key Information

|  |  |
| --- | --- |
| Study Name: |       |
| Study Site/s: |      |
|  |      |
| Target Number of Study Subjects (if applicable): | Minimum:       Maximum:       |
|  |  |
| Name of Site Principal Investigator: |      |
| Address: |      |
|  |       |
|  | State:       P/code:        |
|  |
| Responsible HREC: |      |
| Details of Approved ProtocolProtocol Number (or Northern Health Project Number):      |    |
| Version Number: |       |
| Version Date: |        |

1. Funding and/or other support

[Text can be entered here]

1. Special Conditions

[Text can be entered here]