# CLINICAL RESEARCH AGREEMENT

Between [**INSERT SA HEALTH ENTITY NAME] (A.B.N. [INSERT ABN])** of [Insert Address] And

 **[Insert INSTITUTION Name]** **(A.B.N. [INSERT ABN])** of [Insert Address] (‘**Institution’**)

 (jointly the ‘**Parties’** and each individually a ‘**Party’**)

# RECITALS

A The Parties have identified a particular clinical research activity as outlined in the Schedule (‘the **Study’**) in which they desire to collaborate.

B The Parties acknowledge that the Study is research-orientated and that the outcome of the Study and its ability to produce commercially useful results are not guaranteed.

C The Parties agree to contribute to and undertake the Study in accordance with the following terms and conditions.

# OPERATIVE PART

## 1.0 Definitions

1.1 In this Agreement the following terms have these meanings unless the contrary intention clearly appears:

**‘Agreement’** means this agreement including any schedules, annexures, appendixes and any amendment to it in writing.

**'Background IP'** shall mean Intellectual Property developed prior to or independently of the Study which any of the Parties has agreed to contribute to the Study, including (a) Intellectual Property subsisting in Background Materials and (b) Background Intellectual Property identified in the Schedule;

**Background Material**means any physical, electronic, mechanical, biological or chemical materials (including any tissue, blood or other bio specimen, or any software) belonging to or under the control of a Party which any of the Parties has agreed to contribute to the Study, including as set out in the Schedule;

‘**Business Day’** means any day that is not a Saturday, Sunday or a public holiday in South Australia;

**‘Commercialisation’** includes the use, sale, marketing, distribution, production, licensing, practical application or other commercial application of Study IP including the provision or exploitation of a product, process, or service reliant on that Intellectual Property or to licence a third party to do any of these things;

**‘Completion Date’** shallbe the date identified as the completion date in the Schedule.

**‘Confidential Information**' means and includes any information that by its nature is confidential, is designated by a Party as confidential or the recipient knows or ought to know is confidential but does not include information which:

1. is trivial or obvious;
2. is or becomes public knowledge other than by breach of this Agreement;
3. was known by the recipient as at the date of this Agreement;
4. has been independently developed or acquired by the recipient;
5. is required to be disclosed in compliance with applicable law, government regulation or a court order; or
6. is disclosed for the purposes of monitoring by the HREC,

where the burden of establishing any of the exceptions referred to in (c) or (d) shall be upon the recipient. Confidential Information does not include this Agreement;

**'Contribution'** shall mean the financial and in-kind (including, but not limited to, staffing, use of resources, premises and facilities, capital equipment purchases, Background Materials and Background Intellectual Property) contributions each Party has agreed to devote to the Study in the Study Application and as set out in the Schedule;

**‘Effective Date’** shallbe the date identified as the effective date in the Schedule.

**‘Good Clinical Practice’** means the 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, or its replacement;

**‘GST’** means the tax imposed by the GST Law;

**‘GST Law’** has the meaning attributed to that term in the *A New Tax System (Goods and Services Tax) Act* 1999;

**‘HREC’** means the SA Health Human Research Ethics Committee or another suitable Human Research Ethics Committee recognised under the mutual recognition arrangements of SA Health reviewing the Study as set out the Schedule.

**'Intellectual Property'** includes all copyright and neighbouring rights, all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trademarks (including service marks), registered designs, confidential information (including trade secrets and know how) and circuit layouts, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields as defined in Article 2 of the World Intellectual Property Organisation Convention of July 1967;

**‘Laws’** means the law in force in Australia including the common law and all present and future legislation (both State and Federal) and all amendments to them and re-enactments of them and all regulations and by-laws, orders and proclamations made pursuant to them;

**‘Parties’** mean the Parties to this Agreement and their respective successors and permitted assigns, and **‘Party’** means any one of them.

“**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 a natural person whose identity is apparent, or can reasonably be ascertained, from the information or opinion;

**‘Principal Investigator’** means the lead investigator identified in the Schedule taking overall responsibility for the conduct and management of the Study.

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

**‘Protocol’** means the document attached as an appendix to this Agreement which describes the objective(s), design, methodology, statistical considerations and organisation of the Study, as amended from time to time, as agreed by the parties, and most recently approved by the HREC.

**‘Regulatory Authority’** means statutory authority which has jurisdiction over the conduct of the Study at the Study Site;

**‘Research Governance Officer/s’** means any officer appointed by SA Health authorised to conduct site specific assessments and manage research governance requirements on behalf of SA Health;

**‘SA Health’** means the institutions and administrative units comprising the South Australian Government health portfolio, including:

* + - * 1. the Minister for Health and Wellbeing;
				2. the Department for Health and Wellbeing;
				3. Wellbeing SA;
				4. a hospital incorporated under the Health Care Act 2008 (SA); and
				5. SA Ambulance Service.

**‘Study’** means the Study detailed in the Schedule and the Study Plan.

**‘Study Results’** means any research data, research papers and documents, trial and test results, experiments, products and items and which includes any and all improvements, enhancement, improvement, development, modification or adaptation of Background IP created or developed by one or both of the Parties in carrying out the Study.

**‘Schedule’** means a Schedule to this Agreement;

**'Study IP'** shall mean Intellectual Property, including any Study Results, arising out of or developed in the course of carrying out the Study;

**‘Tax Invoice’** has the meaning attributed by the GST Law; and

**‘Taxable Supply’** has the meaning attributed by the GST Law.

## 2.0 Construction and Interpretation

2.1 In this Agreement, unless the context otherwise requires:

2.1.1 a reference to this Agreement is a reference to this Agreement as amended, varied, novated or substituted from time to time;

2.1.2 In the interpretation of this Agreement no rules of construction shall apply to the disadvantage of one party on the basis that that party put forward the Agreement or any part thereof;

2.1.3 a word importing the singular includes the plural and vice versa, a word importing a gender includes each other gender and words denoting individuals shall include corporations, firms, authorities, unincorporated associations and instrumentalities;

2.1.4 a reference to a party to this Agreement or any other instrument includes that party's executors, administrators, successors and permitted assigns;

2.1.5 where a word or phrase is given a defined meaning in this Agreement, any other part of speech or other grammatical form in respect of such word or phrase shall have a corresponding meaning; and

2.1.6 a paragraph number, schedule number, annexure number or appendix number is a reference to a paragraph of, or schedule, annexure or appendix to, this Agreement.

2.2 This Agreement constitutes the entire agreement between the Parties and supersedes all prior communications, negotiations, arrangements and agreements, either oral or written, between the Parties with respectto the subject matter of this Agreement.

2.3 Any modification, alteration, change or variation of any term and condition of this Agreement (including all the Schedules and Appendixes) shall only be made in writing and shall only be effective upon being executed by both Parties.

2.4 Any heading, index, table of contents, or marginal note used in this Agreement is for convenience only and shall not affect the interpretation of this Agreement.

2.5 In the event of any conflict or inconsistency the following order of precedence shall apply (in descending priority):

* + 1. the terms and conditions of the clauses of this Agreement;
		2. the Schedule; and
		3. the Appendixes to the Schedule

## 3.0 Conduct of the Study

* 1. The Parties agree to undertake and work diligently towards the successful completion of the Study in accordance with the details in the Schedule and the Protocol.
	2. The Study shall commence on the Effective Date.
	3. Without limiting any other term of this Agreement, each Party agrees to carry out its obligations under this Agreement and conduct the Study in accordance with:
		1. any requirements specified in the Schedule;
		2. any requirements specified in the Protocol;
		3. any condition of the HREC and Research Governance Officer/s;
		4. all applicable Laws (including Privacy Laws in the case of the Institution); and
		5. the *National Statement on Ethical Conduct in Human Research (2007, updated 2018) and The Australian Code for Responsible Conduct of Research 2018* (as varied or replaced by the National Health & Medical Research Council, the Australian Research Council and Universities Australia).
		6. Good Clinical Practice (GCP) standards, where applicable; and
		7. For conduct of the project involving SA Health Institutions, all applicable SA Health policy directives, guidelines and standards.
	4. Each Party must:
		1. obtain and comply with all required authorisations from government agencies and ethics committees which are required for the Study; and
		2. not knowingly infringe, and use its best endeavours not to infringe, the Intellectual Property rights of any person in carrying out the Study.
	5. Any variation to the Study, including to a Party’s Contributions, must be agreed to by the Parties in writing.
	6. The Parties will regularly hold meetings, at such times as mutually agreed, to update the other on progress of the Study. A final report in relation to the Study will be compiled and signed off by an authorised representative of each Party prior to the Completion Date or such later date as agreed by the Parties.

**4.0 Study Contributions**

4.1 The Parties agree to make available their Contribution in the form and at the times as detailed in the Schedule.

4.2 There will be no financial obligation and no funding of any sort required from each Party for the conduct of the Study other than as set out in the Schedule.

4.3 Where the Contribution is Background Material, the Parties must ensure that they use the Background Material solely for the purpose of the Study and in accordance with all applicable laws, regulations, codes and guidelines.

4.4 Where any Contribution is overdue by more than ten (10) Business Days the non-defaulting Party reserves the right to suspend the Study or withhold progress reports until payment is made.

4.5 The Parties acknowledge that the Contributions are exclusive of GST. If GST is payable in relation to any Taxable Supply, the Party receiving that Taxable Supply (the Recipient) shall pay, in addition to and at the same time as the Contribution for that Taxable Supply, the GST payable on that Taxable Supply except that the Recipient is not obliged to pay any GST until the Recipient receives a Tax invoice in relation to that Taxable Supply.

## 5.0 Ownership and Exploitation of Intellectual Property

5.1 Ownership of Background IP is not transferred by virtue of this Agreement. All Background IP remains the property of the Party that makes it available for the purpose of carrying out the Study. Each Party hereby grants to the other Party for the Term a non-exclusive, fee and royalty-free licence to use its Background IP as necessary to carry out the Study (other than for Commercialisation) only. No representation or warranty is made or given in relation to Background IP but to the best of its knowledge, each Party acknowledges that as at the Effective Date, when used in accordance with the terms of this Agreement, will not infringe any third party Intellectual Property rights.

5.2 The Parties agree that all rights, title and interest in the Study 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 Study IP, the relevant Parties will own the Study IP in shares proportionate to their respective intellectual contributions to the development or creation of that Intellectual Property

* 1. In the case of jointly owned Study IP, neither Party may:
		1. grant a licence of its share of any Study IP; or
		2. assign its share of the Study IP,

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

5.4 The Parties agree that if at any stage during the course of the Study a Principal Investigator or other researcher involved in the Study becomes aware of any commercially valuable Intellectual Property, the Party employing or engaging the Principal Investigator or other researcher shall notify the other Parties in writing (marked confidential) as soon as possible. The Parties will consult and decide what, if any, measures should be taken to protect the identified Study IP, what options are available for Commercialisation of, and, who will commercialise the Study IP, and, to fairly share in any commercial return associated with the Study and the Study IP.

5.5 In coming to a decision on how Study IP can best be commercialised and the manner of distribution of proceeds for the fair share of any commercial return, the parties will take into account the intellectual input of each party to the creation of the Study IP.

5.6 Each Party hereby grants to the other Party a non-exclusive, non-transferable, perpetual, fee and royalty-free, worldwide licence to use the Study IP it owns for the purposes of the Study and for non-commercial research, education and teaching purposes.

5.7 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 5 before the student commences any Study activities.

* 1. Each Party shall use all reasonable efforts to ensure that any reports, software or other works or inventions containing or embodying the Background IP or Study IP do not contain Intellectual Property belonging to third parties who have not sanctioned that use.
	2. If it is known or suspected by a Party that such third-party Intellectual Property are used or incorporated into Background IP or Study IP, then that Party shall notify the other Party of the full extent of that knowledge or suspicion.

## Protection of Study Intellectual Property

6.1 Each Party agrees to promptly notify the other Party of:

1. any development which that Party believes may require that action be undertaken to ensure the protection of Study IP, under a statutory regime or in any other manner; and
2. any actual or suspected infringement of Study IP which it becomes aware of.

6.2 The Parties shall use their best endeavours to agree upon the necessity and manner for protecting Study IP and the necessity for any action in relation to infringements of Study IP.

6.3 Each Party hereby agrees to prepare and execute all such documents as are reasonably required to ensure the appropriate protection of Study IP and action against infringements of Study IP. All costs associated with any course of action agreed between the Parties will be borne by the Parties in a manner to be agreed in writing.

**7.0 Personal Information**

7.1 Without limiting any other provision of this Agreement, all Parties must comply with

7.1.1 the [South Australian Government Information Privacy Principles](https://www.dpc.sa.gov.au/resources-and-publications/premier-and-cabinet-circulars/DPC-Circular-Information-Privacy-Principles-IPPS-Instruction.pdf) (“**IPPs**”), as if each Party were an “agency” for the purposes of the IPPs, in relation to all Personal Information collected, received, created or held by it in connection with this Agreement; and

7.1.2 the SA Health Privacy Policy Directive (a copy of which can be found at [www.sahealth.sa.gov.au](http://www.sahealth.sa.gov.au)).

7.2 The Parties must ensure that access to Personal Information is limited to those who need it for the purposes of carrying out their duties in the Study for the purpose of this Agreement.

7.3 The Parties must not obtain access to, record, retain amend or disclose Personal Information except if and to the extent:

7.3.1 necessary to comply with obligations under this Agreement; or

7.3.2 expressly authorised by the HREC and SA Health; or

7.3.3 it is in accordance with any Parliamentary or constitutional convention; or

7.3.4 it is permitted under the *Health Care Act 2008* (SA) or the *Mental Health Act 2009* (SA); or

7.3.4 required by Law.

and must ensure that any Personal Information is protected against loss, unauthorised access, use, modification, disclosure or other misuse.

7.4 A Party must promptly notify each other Party if it fails to comply with this clause 7 or if it becomes aware of any actual or threatened disclosure of or unauthorised access to Personal Information.

## 8.0 Publications

8.1 Any of the Parties may publish the results of work performed in relation to the Study provided that a draft of the proposed publication is first submitted to each other Party for comment.

8.2 A Party may embargo a publication only if that Party reasonably believes that the publication discloses Confidential Information owned by it or discloses commercially sensitive Study IP. Publication of Study IP may only be restricted for a period of up to two years or the full protection of that Study IP, whichever is the earlier.

8.3 A Party receiving a proposed publication has thirty (30) calendar days, from the date it receives the draft, to review the draft and provide written reasons for any embargo to or requested alterations to the proposed publication. If a written notification is not received within such thirty (30) calendar day period, written consent to publish the proposed publication shall be deemed to have been provided.

8.4 Each publication shall make reference, if requested, to the involvement of each Party in the Study.

8.5 Each Party agrees that any publication related to the Study will be made in accordance with the *Australian Code for the Responsible Conduct of Research* and that it will not infringe the moral rights of any person in any such publication unless the relevant consents are obtained.

**9.0 Public Statements**

9.1 Each Party shall obtain approval, in writing, from the other Party for any press statements or promotional statements regarding the Study before the statements are released, unless the statement or disclosure is required by:

### (1)  Law;

### (2)  any policy, guideline or direction of government or any government department or agency;

### (3)  any Regulatory Authority; or

(4)  is, in the absolute discretion of the Minister for Health and Wellbeing, Department for Health and Wellbeing or any government official, reasonably necessary in the public interest or to protect the health and safety of any individual.

## 10.0 Confidential Information

10.1 Each Party agrees that it will only use Confidential Information for the purposes of this Agreement and that it will keep secret and confidential and not disclose:

1. any Confidential Information pertaining to the Study; or
2. any Confidential Information owned or supplied by the other Party to any person other than such of its employees, sub-contractors and agents who reasonably require access to that Confidential Information for the purposes of this Agreement and who have been informed of and have agreed to be bound by the obligations of that Party pursuant to this Agreement.

10.2 The obligations imposed upon a Party by this clause shall not apply where:

1. that Party has received the prior written permission of the other Party with respect to the disclosure of that Confidential Information;
2. the Confidential Information has been disclosed in the process of protection of Study IP pursuant to clause 5;
3. the Confidential Information is disclosed in accordance with clause 7; or
4. the Confidential Information is disclosed as required by law provided that the disclosing Party disclose the minimum Confidential Information required and immediately inform the other Party of such disclosure.

10.3 The Institution acknowledges that SA Health may also disclose Confidential Information:

 (a) to Parliament, the Governor, Cabinet or a Parliamentary or Cabinet committee or sub-committee;

 (b) to any agency, authority, instrumentality, Minister or officer of the State of South Australia to whom it is customary to disclose the Confidential Information (whether or not SA Health is legally obliged to do so); or

 (c) for the purposes of prosecuting or defending any legal proceedings.

10.4 The obligations of confidentiality imposed on a Party by this Clause 9 will survive the expiration or termination of this Agreement.

**11.0 Reasonable Delay**

A Party will not be responsible for any delay in performance or non-performance due to any cause beyond the reasonable control of that Party provided that upon such event, the affected Party shall promptly notify the other Party in writing stating the cause of the delay and the effect upon that Party’s performance and take all action within its power to comply with this Agreement as fully and promptly as possible.

**12.0 Warranties and Limitation of Liability**

12.1 Each Party will exercise all reasonable care and diligence in carrying out its obligations under this Agreement and in relation to the Study, but to the fullest extent permitted at law each Party excludes all warranties, conditions or terms, implied in fact or at law, including any warranties that the Study IP are of merchantable quality or are fit for a particular purpose. Each Party uses the Study IP at its own risk in all things.

12.2 To the full extent permitted by applicable law a Party will not be liable to any other Party for any indirect, consequential, special, incidental or punitive damages of any kind, including but not limited to, economic loss, loss of profit, loss of goodwill, loss of use, loss of income, loss of rental or other benefit, loss of production, loss of actual or potential business opportunity or loss of reputation, whether or not such loss, or the possibility of such loss, was foreseeable, could have been contemplated by, or was notified to, the other Party.

12.3 Each Party (the ‘Indemnifier’) will at all times indemnify each and every other Party, its officers, employees and agents (in this clause referred to as ‘Those Indemnified’) from and against any loss (including reasonable legal costs and expenses on a solicitor/own client basis) or liability incurred or suffered by any of Those Indemnified arising from any claim, suit, demand, action or proceeding by any person against any of Those Indemnified where such loss or liability was caused by an unlawful or negligent act or omission by the Indemnifier, its officers, employees or agents in connection with this Agreement.

12.4 An Indemnifier's liability to Those Indemnified under clause 12.3 will be reduced proportionally to the extent that any willful, unlawful or negligent act or omission by Those Indemnified caused or contributed to such loss or liability.

12.5 The Institution warrants that it will maintain or cause to maintain at its own cost, adequate public liability insurance and professional indemnity insurance as appropriate in connection with its activities under this Agreement and workers compensation insurance in accordance with applicable legislation. The Institution shall provide certificates of currency for all relevant insurances upon request by SA Health.

12.6 SA Health warrants that SA Health is entitled to the benefits of the South Australian Government Insurance and Risk Management arrangements administered by the South Australian Government Financing Authority in respect of its activities under this Agreement.

## 13.0 Term and Termination

13.1 This Agreement commences as of the Effective Date and, unless terminated earlier, will expire on the Completion Date (“**Term**”). Any right which by its nature extends beyond the Term of this Agreement shall survive termination of this Agreement.

13.2 This Agreement may be terminated by the mutual agreement of the Parties in writing.

13.3 Either Party may terminate the Agreement by giving twenty eight (28) calendar days prior written notice to the other Party.

13.4 Without limiting the generality of any other clause in this Agreement, a Party (the ‘terminating Party’) may terminate this Agreement where:

* + 1. any other Party (the ‘defaulting Party’) is in breach of any term of this Agreement and such breach is not remedied within thirty (30) calendar days of the terminating Party notifying the defaulting Party of the breach;
		2. the other Party is unable to pay its debts when such debts fall due or becomes subject to any form of administration; or
		3. any other Party ceases or threatens to cease to carry on its business in the normal manner.

13.5 Where this Agreement is terminated on the basis of a breach by a Party (‘Breaching Party’), the Breaching Party, upon the request of the other Parties, will provide the other Parties with a licence to the Study IP to continue the Study.

## 14.0 Disputes

14.1 The Parties must work in good faith to resolve any dispute between them arising from this Agreement.

14.2 Any dispute shall initially be referred to the nominated representatives of each Party for resolution. If such dispute is not resolved within five (5) Business Days, the dispute shall be referred to a meeting of the Managing Director, Chief Executive Officer or equivalent of the Parties, or delegate of each Party.

14.3 If the dispute remains unresolved after a period of sixty (60) calendar days after the second meeting referred to in clause 13.2, the Parties shall agree upon an appropriate mediator. Failing agreement the Law Society of South Australia shall appoint a mediator. Agreement as to the allocation of costs shall be determined through mediation.

14.4 A Party may not commence court proceedings until sixty (60) calendar days after referral to a mediator pursuant to clause 13.3 except that nothing in this clause shall prevent any Party from seeking urgent interlocutory relief through courts of appropriate jurisdiction.

## 15.0 Notices

## 15.1 A “notice” means:

##  15.1.1 a notice in writing; or

###  15.1.2 a consent, approval or other communication required to be in writing under this

###  Agreement.

## A notice must be signed by or on behalf of the sender addressed to the recipient and:

## delivered to the recipient’s address;

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

## transmitted by email to the recipient’s email address.

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

## on the day of delivery if delivered before 5.00 pm on a Business Day, otherwise on the next Business Day;

## if sent by pre-paid mail, on the third Business Day after posting; or

## on the day the email is sent, if transmitted by email before 5.00pm on a Business Day and the sender does not receive a transmission error message.

## 15.4 The address and email address of each Party are as set out in the Schedule.

## 15.5 A Party may from time to time notify its change of address or email address by written notice to the other party.

## 16.0 Miscellaneous

16.1 Auditor-General

 Nothing in this Agreement derogates from the powers of the Auditor-General under the *Public Finance and Audit Act 1987* (SA).

16.2 Costs

##  Each Party will bear its own costs of and incidental to the negotiation, preparation and execution of this Agreement.

16.3 Relationship

 The Parties are independent contracting parties, and nothing in this Agreement makes any Party the employee, partner, agent, legal representative, trust or joint venture of the 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 the other.

16.4 No Assignment

 This Agreement shall be binding upon the Parties and their successors and permitted assigns. No Party shall sell, assign or otherwise dispose of any of its rights or obligations hereunder without the prior written consent of the other Party.

16.5 Waiver

 A party waives a right under this Agreement only by written notice to that effect. Nothing else done or omitted to be done by a party in relation to the party’s rights under the Agreement will have the effect of a waiver.

16.6 Severability

 If any provision or part of a provision of this Agreement is invalid or unenforceable in any jurisdiction:

16.6.1 the provision must be read down for the purposes of the operation of that provision in that jurisdiction, if possible, so as to be valid and enforceable; or

16.6.2 if the provision cannot be read down, it must be severed if it is capable of being severed without affecting the remaining provisions of this Agreement or affecting the validity or enforceability of that provision in any other jurisdiction and the parties must consult in good faith to determine whether any amendment or substituted provision is required.

16.7 Proper Law and Jurisdiction of the Courts

16.7.1 The laws in force in South Australia apply to this Agreement.

16.7.2 The courts of South Australia have exclusive jurisdiction to determine any legal proceedings in relation to this Agreement. Any proceeding brought in a Federal Court must be instituted in the Adelaide Registry of that Federal Court.

16.8 Other Activities

This Agreement does not preclude any Party engaging in research or other activities similar to the Study or its subject matter.

16.9 Counterparts

This Agreement may be signed in any number of counterparts which together will constitute one agreement.

16.10 Electronic Execution

Each Party may communicate its execution of this Agreement by successfully transmitting an executed copy of this Agreement by email to the other Party.

16.11 Force Majeure

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 (a Force Majeure Event), the affected party shall promptly notify the other party in writing, giving details of the Force Majeure Event, the acts affected by the Force Majeure Event and the extent to which they are affected, the expected duration of the Force Majeure Event, and performance of such acts shall be excused for the period of such event provided that if such interference lasts for any period in excess of 30 days either party may, by written notice to the other, terminate this Agreement.

**EXECUTION**

**EXECUTED** as an agreement.

|  |  |
| --- | --- |
| **SIGNED** for and on behalf of **[INSERT SA HEALTH ENTITY]** by its duly Authorised Representative in the presence of:………….….………………………Signature………….….………………………Name………….….………………………Date | )))) |

|  |  |
| --- | --- |
| **SIGNED** for and on behalf of **INSTITUTION** by its duly Authorised Representative in the presence of:………….….………………………Signature………….….………………………Name ………….….………………………Date | )))) |

[INSERT FURTHER EXECUTION CLAUSES FOR EACH ADDITIONAL PARTY]

**SCHEDULE**

|  |  |
| --- | --- |
| 1. Title of Study:
 | [Insert Title of Study] |
| 1. Study Overview (see Appendix 1 for Protocol):
 | [Insert Details of Study] |
| 1. Effective Date:
 | [Insert Study Start Date] |
| 1. Completion Date:
 | [Insert Study End Date] |
| 1. Principal Investigator
 | [Insert Name] - [Insert Position] |
| 1. HREC:
 | [Insert Details of HREC Reviewing the Study] |
| 1. Study Research Team:
 | **SA Health** [Insert Name] - [Insert Position]**Institution**: [Insert Name] - [Insert Position] |
| 1. Financial Contributions
 | **SA Health**: [Insert Details]**Institution**: [Insert Details] |
| 1. In-kind contributions:
 | **SA Health:** [Insert Details]**Institution:** [Insert Details] |
| 1. Background Intellectual Property:
 | **SA Health:** [Insert Details]**Institution:** [Insert Details] |
| 1. Background Materials:
 | **SA Health:** [Insert Details]**Institution:** [Insert Details] |
| 1. Contact Details for Notices:
 | **SA Health:** Name & Position: [Insert Name] - [Insert Position]Address: [Insert Address]Email: [Insert Email Address]**Institution**: Name & Position: [Insert Name] - [Insert Position]Address: [Insert Address]Email: [Insert Email Address] |
| 1. Special Conditions:
 |  |

**APPENDIX 1 TO SCHEDULE: STUDY PLAN**

**[Attach Study Plan]**

**APPENDIX 2 TO SCHEDULE: PROTOCOL**

**[Attach Protocol]**