if

 xxxx Health Service

 Government of **Western Australia**

**RESEARCH ACCESS AGREEMENT**

**Details of the parties**

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

|  |  |
| --- | --- |
| Date of Agreement: | **Date of last party to sign** |

Legal and Legislative Services

Department of Health

189 Royal Street

EAST PERTH WA 6004

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This agreement is made between the Health Service Provider and the Institute

**RECITALS:**

According to this Agreement:

1. The purpose of this Agreement is to set out the arrangements under which the Institute’s Personnel may have access to the premises, facilities and services controlled by the Health Service Provider for the purposes of conducting Research.
2. The Parties have agreed to set out their respective rights and obligations in this Agreement.

**OPERATIVE PROVISIONS**

1. **INTERPRETATION**
	1. In this Agreement, unless the context otherwise requires:

**Adverse Event** has the meaning given in the Good Clinical Practice (GCP) guidelines.

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

**Background IP** means any Intellectual Property which pre-exists the Research or is independently developed outside of the Research that is owned or controlled by a Party and which that Party chooses at its sole discretion to make available for the purpose of carrying out the Research, but excludes the Research Materials.

**Business Days** means a day that is not a Saturday, Sunday or a public holiday in Western Australia.

**Confidential Information** means any information which is confidential within the meaning in the *Health Services Act 2016* (WA) or which the Parties agree in writing is confidential or that 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.

**Coordinating Principal Investigator** means the researcher responsible for the overall conduct of the specific Research.

**Designated Research Areas** means those areas within the Premises as identified and approved by the HSP for the conduct of the Research and which are specified in Item 2 of Schedule 3, excluding those areas that are owned, leased or otherwise controlled by the Institute.

**Facilities** means the resources located within the Designated Research Areas of the HSP specified in Item 3 of Schedule 3.

**Facility Fee** means the fee to be paid by the Institute for the use of the Designated Research Area and/or other services provided by the HSP for the purpose of the Research.

**Facility Agreement** means the written agreement between the Parties setting out the conditions, payment details and other matters concerning Research where a Facility Fee applies.

**Good Clinical Practice (GCP) guidelines** means the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2)as adopted with annotation by the TGA, or its replacement.

**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.

**Head of Department** means the Head or Coordinator of the medical or other professional health service of the Hospital, designated by the HSP.

**Health Service Provider (HSP)** means the body so described on the first page of this Agreement which is a public hospital pursuant to section 8(6) of the *Health Services Act 201*6 under the control of the HSP.

**Human Research Ethics Committee (HREC)** means the committee who has provided ethical review and approval of the research project.

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

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

* + 1. patents, copyright, future copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trademarks, 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
		2. any application or right to apply for registration of any of those rights but excludes moral rights as conferred by the Copyright Act 1968.

**National Police Certificate** means an Australia-wide check of a person's criminal history prepared by the Australian Federal Police, a State or Territory police service, or an agency accredited by CrimTrac.

**Parties** means the parties to this Agreement and **Party** means either one of them.

**Patient** means a patient (of whatever description or type) currently receiving treatment or care from the HSP and, where the context requires, includes Research Participants.

**Patient Record** consists of, but is not limited to, a record of the patient’s medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care.

**Personal Information** has the same meaning as in the *Privacy Act 1988* (Cth).

**Personnel** means the employees, agents and/or authorised representatives of the Parties, including persons holding Honorary appointments with the Institute and, as applicable, students that are enrolled or training at the Institute.

**Policies** means any policies, codes, guidelines (including clinical care guidelines), procedures, protocols, and standards (as amended, superseded or replaced from time to time), adopted by the HSP.

**Premises** means the land and buildings controlled or managed by the HSP but does not include those areas within the HSP that are owned, leased or otherwise controlled by the Institute.

**Principal Investigator** means the HSP staff member responsible for the conduct of the specific Research at the HSP site/s.

**Protocol** means the document which describes the objective(s), design, methodology, statistical considerations and organisation of the specific Research. For Research requiring HREC approval, the Protocol is the version as most recently approved by the Reviewing HREC. Depending on the specific Research, the Protocol may be owned by the Institute, a not-for-profit entity acting through the Institute, or a combination of those entities.

**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 the Research Materials in printed, electronic, oral or other form.

**Publication** has a corresponding meaning to Publish.

**Regulatory Authority** means any person or body which has jurisdiction over the conduct of the Research at the HSP and includes the Australian Health Practitioner Regulation Authority (AHPRA), the TGA and any overseas regulatory authorities who may audit, or require to be audited, any part of the Research.

**Relevant Privacy Law** meansthe *Privacy Act 1988* (Cth) or any other legislation, code or guideline which relates to the protection of Personal Information and which applies in Western Australia.

**Research** means a research project approved by the Reviewing HREC and the HSP in which Research Staff utilise the Designated Research Areas and/or other resources controlled by the HSP, including, but not limited to, clinical wards, rehabilitation areas, and clinical databases containing health-related personal data of Research Participants; the details of which are set out in the relevant Protocol. For the avoidance of doubt, the Agreement does not apply to research conducted on premises owned, leased or otherwise controlled by the Institute.

**Research Materials** means all the materials and information created for the Research including all data, results, biological samples, Case Report Forms (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Research which are discovered or developed as a result of the Research, but excluding the HSP’s ordinary Patient Records.

**Research Participant** means a Patient, a former Patient, or relatives of Patients, or the HSP’s Personnel, recruited to participate in the Research.

**Research Staff** means, in the context of the Research, the Institute’s Personnel. For the avoidance of doubt, reference in this Agreement to Research Staff does not include the Principal Investigator.

**Reviewing HREC** means the Human Research Ethics Committee which is recognised by the HSP and which reviews the Research on behalf of the Institute.

**Schedule** means the schedules attached to this Agreement.

**Serious Adverse Event** has the meaning given in the GCP guidelines.

**Service Agreement** means a written agreement between the Parties setting out the terms and conditions for a defined scope of work to be undertaken by the HSP at the request of the Institute.

**State** means the State of Western Australia.

**TGA** means the Therapeutic Goods Administration of the Commonwealth of Australia or any successor body.

**Working With Children Legislation** means the *Working with Children (Criminal Record Checking) Act 2004* (WA) and *Working with Children (Criminal Record Checking) Regulations 2005* (WA).

* 1. In this Agreement, unless the contrary appears:
1. words in the singular number include the plural and vice versa;
2. words importing a gender include any other gender;
3. where word or phrase is given a particular meaning, other parts of speech and grammatical forms of that word have corresponding meanings.
4. a reference to “GST”, “input tax credit”, “supply”, “tax invoice” and “taxable supply” have the meanings given to those expressions in the *A New Tax System (Goods and Services Tax) Act 1999.*
	1. This Agreement supplements, but does not replace, other extant agreements affecting the relationship between the Parties (e.g. Shared Facilities Agreement). The Agreement does not override the existing policies of either Party, as expressed in policy statements, codes of conduct or guidance applying to either Party’s employees.
	2. Unless contrary to the sense or context, a reference to a party includes that party’s executors, administrators, personal representatives, successors and assigns, and if a party comprises two or more persons, the executors, administrators, personal representatives, successors and assigns each of those persons.
5. **AGREEMENTS BETWEEN INSTITUTE AND THIRD PARTY**
	1. The Institute will notify the HSP in writing of all agreements between the Institute and third parties (**Third Party Agreement**) which relate materially to the Research.
	2. Subject to **clauses 2.3, 2.4** and **2.5**, in the event any inconsistency is identified by the Institute between the terms of the Agreement and a Third Party Agreement the Third Party Agreement will prevail to the extent of the inconsistency but, to the extent that the Agreement and the Third Party Agreement are consistent, without affecting the continued operation of the Agreement.
	3. The Institute will, at least 60 days before the proposed starting date of the Research, provide the HSP with:
6. documentation setting out the clause(s) in the Third Party Agreement and the Agreement which the Institute holds to be mutually incompatible; and
7. a request that the HSP approves the specified clauses in the Third Party Agreement having precedence over the specified clauses in the Agreement.
	1. On receipt of the material referred to in **clause 2.3**, the HSP will, as soon as reasonably practical, respond in writing to the Institute in respect of the Institute’s request referred to in **clause 2.3(b)**.
	2. If the HSP forms, at its sole discretion, the opinion that the terms of a Third Party Agreement materially prejudices the HSP’s rights under the Agreement, or conflicts with the HSP’s Policies, the HSP may, by notice in writing to the Institute, decline to approve Research that is subject to that Third Party Agreement.
	3. For the avoidance of doubt, and notwithstanding any other provision in this Agreement, this Agreement shall only apply where the Parties conduct Research utilising the Designated Research Areas and/or other resources controlled by the HSP.
8. **REPRESENTATIVE**
	1. To ensure the efficient operation and performance, and to review and evaluate the effectiveness of this Agreement at the HSP, the Parties will nominate liaison officers in respect of this Agreement (refer Schedule 1).
	2. The liaison officer of a Party will be responsible for:
9. managing, overseeing or co-ordinating that Party’s relationship with the other Party;
10. identifying any commercial issues that arise between the Parties and referring those issues to the appropriate person within the respective Party; and
11. co-ordinating the exchange of information between the Parties.
	1. For the purposes of this Agreement, the respective liaison officer of the HSP and the Institute, nominated under **clause 3.1**, may:
12. exercise a power specified in this Agreement as being exercisable by the HSP or the Institute, other than the power in clause 3.2;
13. perform an act or do a thing specified in this Agreement as being required or permitted to be done by the HSP or the Institute; and
14. give an approval specified in this Agreement as being required or permitted to be given by the HSP or the Institute.
15. **HSP PERMITS PHYSICAL ACCESS TO PREMISES BY THE RESEARCH STAFF**
	1. Subject to this clause 4, the HSP permits the Research Staff to have access to, and use of, only the following:
16. the Designated Research Areas;
17. the Facilities; and
18. subject to 4.3, other areas of the HSP specified in item 4 of Schedule 3,

in accordance with the terms and conditions set out in this Agreement provided that such access and use are:

1. required for, and are part of, the Research and is agreed to by the HSP’s liaison officer; and
2. in accordance with the terms and conditions set out in this Agreement.
	1. Access to the Premises by the Research Staff will be limited to the Designated Research Area and other areas identified in the relevant Protocol, unless otherwise agreed by the Parties in writing.
	2. Use of and access to the Designated Research Areas, the Facilities, and other areas of the HSP for Research must be approved in writing in accordance with item 4 of Schedule 3 by the HSP’s liaison officer.
	3. In addition to clause 4.2, use of and access to other areas of the HSP must be approved in writing in accordance with item 6 of Schedule 3 by the relevant Head of Department.
	4. The HSP will use its best endeavours to maintain, at the HSP’s expense, the Designated Research Areas and Facilities in good working order, and ensure that they are in a safe condition and compliant with the requirements of regulations and the relevant Policies. Research Staff shall not, in any manner, prevent, restrict or inhibit the HSP from undertaking its responsibilities in this regard.
	5. The Head of Department shall inform the Institute of the Policies relating to infection control, including Policies relating to access to the Premises by persons with a communicable disease, that Research Staff must comply with, including Operational Directive 0388/12 “Health Care Worker Immunisation Policy” (issued under the Public Health Policy Framework), or its replacement.
	6. The Institute must take all reasonable measures to ensure that the Research Staff who come into contact with Patients comply with the infection control Policies of the HSP.
	7. If a Research Staff member fails to comply with the HSP’s infection control Policies the HSP may, at its sole and absolute discretion, invoke the provisions of **clause 6.2**.
	8. The Institute shall ensure that Research Staff members have a *methicillin-resistant staphylococcus aureus* (MRSA) clearance if the Research Staff member has been a patient, or a researcher or has worked, in any hospital or residential care facility outside of Western Australia in the last 12 months.
	9. The Institute shall ensure that each member of the Research Staff discloses to the Head of Department if they have a medical or health condition which might affect the health or safety of other persons whilst on the Premises.
	10. The Institute shall ensure each Research Staff member provides evidence to the HSP when required for audit purposes of a current National Police Certificate before entry onto the Premises for the purpose of the Research.
	11. The Institute shall ensure each Research Staff member is aware of their obligation to comply with the provisions of the Working With Children Legislation where relevant, and provide evidence of screening to the HSP as required for audit purposes.
	12. The Institute shall ensure Research Staff are aware of their obligation to:
3. obey the directions and orders of the HSP’s Personnel and comply with the HSP’s rules, regulations and Policies, including the protocols and procedures applicable to the Premises, as advised by Head of Department; and.
4. take all reasonable measures to read, understand, and comply with the relevant Policies.
	1. The HSP shall arrange appropriate orientation for the Research Staff and shall provide Research Staff with access to copies of the relevant Policies which relate to or concern the use of the Facilities at the Premises.
	2. The HSP shall be responsible for the appropriate induction of the Research Staff with respect to:
5. security;
6. emergency; and
7. safety

Policies and procedures in respect of the Premises and Facilities.

For the avoidance of doubt, the Institute is responsible for ensuring Research Staff comply with relevant occupational health and safety policies and procedures.

* 1. The HSP will provide for the emergency care of Research Staff, according to the facilities available, where they suffer an accident or illness whilst on the Premises, in accordance with the usual conditions relating to such visiting Personnel at the Premises.
1. **HSP PERMITS ACCESS TO HSP RECORDS BY THE RESEARCH STAFF**
	1. Research Staff may apply to the HSP’s liaison officer, and if applicable the Reviewing HREC, for permission to access and use a Research Participant’s information, including personal information, a Research Participant’s tissue, or data held by the HSP relating to the Research Participant (including the Research Participants Patient Record).
	2. The HSP’s liaison officer, and if applicable the Reviewing HREC, may grant permission to the Research Staff to access and use a Research Participant’s information only where the following conditions are satisfied:
		1. The Research Participant has given express consent for the access and use of the relevant information, tissue or data, or the access and use of the relevant information, tissue or data is otherwise authorised by law; and
		2. The access and use of the relevant information, tissue or data is in accordance with the relevant HREC and HSP’s approval.
	3. Where an application is made to the HSP, the HSP’s liaison officer and the Reviewing HREC, and one or two but not all refuse to grant permission to the Research Staff, the Institute may utilise the **clause 17**.
2. **PATIENT CARE**
	1. The Institute shall ensure that the Research Staff abide by the HSP’s decisions regarding the needs of, and the care for, Patients.
	2. The responsibility for Patient care lies with the HSP, and the relevant Head of Department or the HSP’s liaison officer may at any time, and at its sole discretion, exclude a Research Staff member from the Premises to maintain Patient safety. If the HSP makes a determination in accordance with this clause, the HSP liaison officer will endeavour to promptly notify the Institute of that determination.
3. **RESEARCH ACTIVITY**
	1. The Parties agree to work collaboratively to ensure high standards of research management, administration and governance. The Parties agree to comply with all legal and ethical considerations, including all conditions attached to Reviewing HREC and HSP approvals concerning the conduct of the Research.
	2. The Agreement applies to any Research including, but is not restricted to, any Research involving human participants, whether as Patients or relatives of Patients, healthy volunteers, or members of staff. For the avoidance of doubt, it also includes non-medical Research involving use of health information or human tissue derived from Patients or staff of the HSP, their relatives or carers, or involving the use of any the HSP’s staff, resources or facilities. It applies to Research requiring direct contact with human participants, or the use of tissue, organ or fluid samples, whether taken specifically for the Research, stored from previous studies, or surplus to clinical requirements, or if the Research Staff require access to Confidential Information held by the HSP.
	3. For Research regulated under the Therapeutic Goods legislation where the Institute is identified as the sponsor, the Institute must comply with, and conduct the Research in accordance with the following, in the following order of precedence:
4. any requirements of relevant Commonwealth or State or Territory laws or of Regulatory Authorities;
5. any condition of the Reviewing HREC; and
6. the Protocol;

and additionally, as applicable:

1. the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007) or its replacement, and any other relevant NHMRC publication or guideline that relates or may relate to human research;
2. the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996;
3. the GCP Guidelines and any other TGA publication or guideline that relates or may relate to clinical trials, or other such regulations or guidance governing the conduct of clinical research in Western Australia.
	1. For Research covered by this Agreement, formal, approval by the Reviewing HREC and the HSP is required before the Research can begin. The Institute shall ensure that Research Staff do not undertake any Research or surveys which involve the HSP, its Patients, Personnel or Premises, until all of the required approvals and authorisations, including the Reviewing HREC’s, have been provided in writing.
	2. If data is being requested to perform health-related research involving Indigenous people, ethics approval must also be sought from the Western Australian Aboriginal Health Ethics Committee (WAAHEC) in accordance with their guidelines. In particular, projects should be submitted to WAAHEC if one or more of the following apply:
4. Aboriginality is a key determinant;
5. data collection is explicitly directed at Indigenous people;
6. Indigenous people, as a group, will be examined in the results;
7. the information has an impact on one or more Aboriginal communities; or
8. Aboriginal health funds are a source of funding.
	1. Certain types of research require specific assessment and approval procedures as set down in national guidelines or legislative requirements. These include clinical trials involving investigational medicinal products, clinical trials involving medical devices, research involving genetically modified organisms (including gene therapy), fetuses or foetal tissue, xenotransplantation and research involving the storage of human tissue. The Parties shall ensure that Research Staff intending to undertake Research falling into these categories are aware of, and follow, the national procedures and relevant HSP, and Institute policies and guidelines.
	2. Where the Research requires a Clinical Trial Notification (CTN) be submitted to the TGA the Parties shall ensure that Research Staff include the HSP as a trial site and the HSP as an approving authority on the CTN.
	3. Unless agreed in writing by both Parties, the Personnel of one Party (first Party) are not authorised to act on behalf of the other Party (second Party).
9. **PRINCIPAL INVESTIGATOR**
	1. Research involving the HSP’s Facilities and/or Patients will have a designated Principal Investigator who must be an employee of the HSP.
	2. The Institute has authorised the Principal Investigator to be the person responsible for the conduct of the Research on a day-to-day basis.
	3. If the Principal Investigator leaves the Research or otherwise ceases to be available then:
10. the Institute must notify the HSP as soon as is possible;
11. the Institute must, as soon as possible, provide a replacement reasonably acceptable to both Parties; and
12. if a replacement cannot be found who is acceptable to both Parties, the HSP may direct the Institute to terminate the Research, and the HSP may terminate this Agreement in accordance with **clause 20.4**.
13. **RESEARCH STAFF**
	1. Subject to **clauses 6.2** and **9.2**, following consultation with the Institute, the HSP may withdraw or exclude Research Staff from the Premises.
	2. In the event of an emergency or adverse situation, the HSP may determine at its absolute discretion to withdraw, exclude or refuse to admit Research Staff to a part of or all of the Premises. If the HSP makes a determination in accordance with this clause, the HSP’s liaison officer will endeavour to promptly notify the Institute of that determination.
	3. The Institute agrees to be responsible for the acts and omissions of the Research Staff in relation to the conduct of the Research, to the extent that such responsibility would attach to the Institute in accordance with its obligations under this Agreement or under the common law on the basis that the Research Staff is acting as an employee, agent or authorised representative of the Institute. Nothing in this clause or Agreement affects any pre-existing contractual or other arrangement which may be in place between the Institute and the Research Staff.
	4. In relation to Research Staff accessing the Premises to conduct Research, the Institute will take reasonable steps to ensure that:
14. Each of the Research Staff have a level of preparation which is sufficient to meet the level of competence required for that aspect of the Research they will be undertaking;
15. Research Staff who provide care to Research Participants in accordance with an approved Research Protocol are, where applicable, registered with the relevant Professional Registration Board, or, if there is no relevant registration board, are eligible for membership of their professional association. If required by the HSP, the Institute will provide evidence of that registration or eligibility for membership on demand.
16. Research Staff, through the Principal Investigator and Coordinating Principal Investigator, notify the HSP and the Reviewing HREC of any required safety reporting (including Serious Adverse Events) that occur during the course of the Research, in accordance with the Protocol, the relevant ethical and regulatory guidelines and with the applicable Policies.
	1. In relation to Research conducted by Research Staff on the Premises, the Parties will cooperate with the Reviewing HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Research.
	2. Either Party will notify the other Party as soon as reasonably practical if it becomes aware of:
17. in respect of Research Staff:
18. a relevant Professional Registration Board or association fining or reprimanding them or requiring the Research Staff member to provide an undertaking to be of good behaviour, or makes conditional, suspends or removes the registration or membership of the Research Staff or the registration or membership lapses;
19. any investigation by a relevant Professional Registration Board or association is commenced against a Research Staff member;
20. any charges or convictions for an offence punishable by imprisonment being made against a Research Staff member;
21. any actual or potential conflict of interest involving a Research Staff member; or
22. any illness or disease that would interfere with Research Staffs ability to treat Research Participants or that is communicable and presents a risk to Patients or other people;

and

1. in respect of any Research Participant, any:
2. adverse incident;
3. serious verbal, or any written complaints received;
4. threats of legal action or any writ, subpoena or summons received;
5. matter which a Research Staff member is obliged to inform his or her indemnity fund, Institute or insurer;
6. referral to the relevant Professional Registration Board or association; or
7. referral to the Health and Disability Services Complaints Office.
	1. The Institute must take all reasonable steps to assist, and use all reasonable endeavours to cause any member of Research Staff to assist, the HSP in inquiring into and resolving any matter arising under or in connection with any matter referred to in **clause 9.6**.
	2. If requested by the HSP, the Institute must, as soon as possible, provide and cause any member of Research Staff to provide, all relevant details of any matters of which the HSP is advised under **clause 9.6** or otherwise becomes aware.
	3. Nothing however requires any member of the Research Staff to disclose information to the HSP where to do so would cause that person to be in breach of his or her obligations to any health or medical defence institute, indemnity fund or insurer, or which may significantly prejudice any claim by that person under that indemnity cover or insurance. In any such circumstances the member of Research Staff must use their best endeavours to obtain the approval of the defence institute, indemnity fund or insurer to disclosure of the information required by the HSP, and must disclose the information to the HSP in accordance with any approval given.
	4. The HSP may, at its sole discretion, terminate the Research if, it cannot be continued independently from the Research Staff that has,
8. a relevant Professional Registration Board or association fining or reprimanding them, or requiring the Research Staff member to provide an undertaking to be of good behaviour, or makes conditional, suspends or removes the registration or membership of the Research Staff, or the registration or membership lapses; or
9. any charges or convictions for an offence punishable by imprisonment being made against a member of Research Staff.
	1. The Institute must take all reasonable steps to ensure that Research Staff wear identification badges at all times when on the Premises, including the Facilities, clearly identifying them as the Institute’s Personnel.
10. **PROVISION OF INFORMATION TO PATIENTS**
	1. In this **clause 10**, references to Patients and Research Participants are to be understood, as the context requires, to include persons with parental responsibility for a child.
	2. For Research involving the recruitment of Patients as Research Participants:
11. all advertising or promotional material intended to attract Research Participants will include a statement to the effect that the Institute is responsible for the Research;
12. informed consent to participate in the Research will be obtained from each Patient prior to their enrolment in the Research and documented using an information and consent document which has been reviewed and approved by the HSP and the Reviewing HREC;
13. where the Institute is the sponsor of the Research, the information and consent documents will include, and be acknowledged in writing by the prospective Research Participant, a statement to the effect that the Institute and the Research Staff are conducting the Research on behalf of the Institute;
14. if requested by the Principal Investigator, the HSP’s Personnel will, subject to this clause, provide information, including printed material supplied by the Institute, concerning the Research, to Patients; and
15. the HSP’s Personnel will, when providing Patients with information about the Research, advise those Patients that the Institute is not part of the HSP or the State’s public health system.
16. **PAYMENTS**
	1. **Facility Fee**
17. In consideration of the use of the Designated Research Areas and Facilities, the Institute will, with prior agreement, pay to the HSP in the time and manner agreed by the Parties as set out in a Facility Agreement, the Facility Fee associated with Research.
18. If the Parties are unable to agree on the Facility Fee for specific Research, then either Party may choose to settle the dispute in accordance with the dispute resolution procedures specified in **clause 17** of this Agreement.
	1. **Supply of Services**
19. Subject to the prior agreement of the HSP and on such terms and conditions that the HSP may specify, the Institute may request the HSP to supply services including but not limited to, pharmacy and radiology. At the HSP’s discretion, the terms and conditions of the supply of such services may be set out in a Service Agreement.
20. For this purpose, the Institute agrees to pay the HSP for those services on receipt of a valid tax invoice, the amount, and by the due date, specified on tax invoice in accordance with the payment instructions specified.
	1. **Goods and Services Tax**
21. The Institute and the HSP each warrant that they are registered under GST Law. Tax invoices must identify the services and supplies for which GST is payable.
22. At the time of payments made in respect of **clauses 11.1** and **11.2** the Institute must also pay to the HSP any amount of GST that the HSP is required to pay in accordance with GST Law. Any amount of GST payable will be payable at the same time as the payment(s) of the Facility Fee or services to which it relates.
23. A written statement given to the Institute by the HSP of the amount of GST that the HSP pays or is liable to pay is conclusive as between the Parties except in the case of an obvious error.
	1. If there is a dispute over the payment of a valid tax invoice, the HSP will reissue an invoice for the undisputed amount which the Institute will pay within 30 days of receiving, while the disputed amount is being finalised.
24. **CONFIDENTIALITY**
	1. Subject to **clause 12.2**, the Parties must not, and must ensure their Personnel do not use or disclose any Confidential Information, other than where and only to the extent such use or disclosure is necessary for the performance of the Research.
	2. Provided that it is otherwise lawful, the Parties may access, use or disclose Confidential Information in any of the following circumstances:
25. for the purposes of complying with internal complaint procedures, accident reporting procedures, quality assurance activities, disciplinary procedures or any applicable policy in relation to patient safety, Adverse Events and/or reportable incidents;
26. for the purposes of complying with the requirements of any Regulatory Authority;
27. for the purposes of the monitoring of the Research by the Reviewing HREC, the Institute and the HSP;
28. where the other Party consents in writing to the disclosure;
29. where the Confidential Information has been independently received from a third party who is free to disclose it;
30. where the Confidential Information has entered the public domain other than as a result of a breach of this Agreement;
31. where release of the Confidential Information is required by law, with notice as soon as reasonably practicable to the other Party;
32. as part of a publication released in accordance with **clause 14**
33. for the purposes of obtaining legal advice or representation;
34. to the Party’s insurer; and
35. to Parliament (including committees of it), the Auditor General, and Ministers of the Crown if legally directed to do so.
	1. Where Confidential Information is disclosed in accordance with **clause 12.2**, the Confidential Information must only be used for the purposes for which it was accessed, used or disclosed.
36. **PRIVACY**
	1. Each Party must ensure that any Personal Information of Research Participants or Personnel it obtains or holds as a result of the conduct of the Research is collected, stored, used and disclosed by it in accordance with all approvals or authorisations given for the conduct of the Research, and all relevant applicable laws.
	2. Each Party will, as soon as reasonably practical after it becomes aware, report to the other Party any unauthorised access to, use or disclosure of Personal Information of Research Participants (“Incident”) of which it becomes aware, and will work with the other Party to take reasonable steps to remedy the Incident.
37. **PUBLICATIONS**
	1. Subject to all authorisations and approvals given, the Institute, Principal Investigator and Research Staff (“Discloser”) involved in the Research have the right to Publish the methods, results of, and conclusions from, the Research, subject to this **clause 14** and in accordance with copyright law.
	2. The Parties acknowledge that a student of the Institute may include the results of the Research in whole or in part in the student’s thesis, in which case the HSP whose Confidential Information and/or Intellectual Property will be prejudiced if it is published in the student’s thesis may reasonably request that thesis be submitted to examiners in confidence. Each party will endeavour to keep any period of restriction to a minimum of not more than 60 days for a student thesis publication to allow the HSP time to protect Confidential Information and/or Intellectual Property.
	3. The HSP’s liaison officer shall notify the Institute and the Discloser in writing of the HSP’s consent or required amendments associated with the removal of Confidential Information in detail within 21 days of receipt of the Publication, and the Discloser (as the case may be) must make any required amendments.
	4. Unless otherwise directed in writing by the HSP, the HSP’s support of the Research shall be acknowledged in all Publications.
	5. If directed in writing by the HSP, the Discloser shall insert the following disclaimer in the Publication: “The views and opinions expressed in this publication are those of the authors and do not necessarily reflect those of the hospital, the health service provider or the Minister for Health.”
	6. The Discloser must submit a copy of the Publication(s) resulting from the Research to the Head of Department and the HSP’s liaison officer and add a copy of the Publication(s) resulting from the Research to the Research Governance Service (RGS) project record within 40 days of being published.
38. **RESEARCH RESULTS AND 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 Research.
	2. Each Party warrants that it either owns, or is properly licensed to use, its Background IP and that it has the right to grant the licence in **clauses 15.3** and such Background IP when used in accordance with this Agreement will not infringe any third-party IP rights.
	3. For Research requiring the use of the HSP Background IP:
39. the HSP is to grant to the Institute a royalty-free, non-transferrable licence to use its Background IP to the extent necessary to carry out the Research for the duration of the Research;
40. notwithstanding **clause 15.2**, the HSP grants to the Institute a non-exclusive, perpetual, royalty-free licence to use (including the right to sub-licence) the HSP’s Background IP in the Research Materials for the purpose of conducting the Research;
41. where the Institute is the Research Sponsor, the Institute must obtain the HSP’s prior written consent of any IP in the Research Materials that it wishes to have vested upon its creation in the Institute and any existing and future IP rights (including all future copyright) contained in the Research Materials it wishes to have assigned to the Institute. The HSP will:

(1) provide consent for the IP in the Research Materials to be vested upon its creation to the Institute and assign that particular existing and future IP right (including all future copyright) contained in Research Materials and impose any conditions as it reasonably sees fit and without any financial consequences for the HSP; or

(2) refuse to provide consent based on reasonable commercial or proprietorial reasons for the IP in the Research Materials to be vested to the Institute upon its creation and that a particular existing and future right (including all future copyrights) contained in the Research Material be assigned to the Institute;

The HSP will inform the Institute within 20 Business Days of any such request from the Institute on whether it consents or not that the particular IP in the Research Materials will be vested to the Institute upon its creation and that the particular existing and future right (including all future copyrights) contained in the Research material be assigned to the Institute.

1. the Institute must promptly disclose and communicate in writing to the HSP full particulars of any IP that the Institute or Coordinating Principal Investigator make, discover or conceive in the course of the Research;
2. the Institute grants to the HSP a non-exclusive, perpetual, irrevocable, royalty-free licence to use the IP in the Research Materials for:
3. non-commercial research, education and training purposes;
4. publications in academic and other journals, subject to **clause 14**; and
5. non-commercial research in conjunction with or as funded by third parties.
6. the Institute shall ensure that its Personnel who assist in the conduct of the Research sign a declaration provided by the Institute in which each of the Personnel acknowledge that all IP that may be developed or acquired during the course of the Research belongs to the Institute and that the Institute can, at its discretion, assign the IP to another party.
	1. Except as otherwise provided by this Agreement (including by not limited to provisions relating to confidentiality, IP and privacy), the HSP may use and present any information concerning the Research for the purposes of non-commercial training, education, evaluation or discussion without the consent of the Institute, other than to the extent that such information is Confidential Information, in which case the HSP must seek the prior written consent of the Institute, which may be withheld at the discretion of the Institute, before disclosing this information.
7. **RESPONSIBLE CONDUCT OF RESEARCH**
	1. In relation to Research conducted on the Premises, the Parties and the Research Staff will comply with the *Australian Code for the Responsible Conduct of Research 2018* (NHMRC, 2018) or its replacement. In cases of alleged research misconduct, each party will be obligated to investigate according to its own requirements and each Party will agree to collaborate and keep the other informed at each stage of the investigation.
	2. Where a case of research misconduct is identified through the initial investigation, the investigation file will be passed to Human Resources department of the employer of the Personnel under investigation. The responsible Party will complete the investigation and deal with any subsequent disciplinary action.
	3. Subject to law, any disciplinary action taken by one Party on a member of staff of the other Party, including disciplinary action that impacts on the staff member’s ability to undertake Research will be formally notified to the other Party.
8. **RESOLUTION OF DISPUTES**
	1. The Parties acknowledge that they wish to make the terms of this Agreement work effectively and are committed to resolving any disputes, controversies or differences (“**Dispute**”) promptly should they arise.
	2. No Party may commence legal proceedings against another in respect of a Dispute arising in relation to this Agreement (except for urgent interlocutory relief) unless the Parties have complied with this clause 16 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 within 28 days of the giving of that notice.
	3. In the event that the Dispute is not settled within 28 days then the Parties are free to pursue any other procedures available at law for the resolution of the Dispute.
	4. Despite the existence of a Dispute, the Parties must continue to perform their respective obligations under this Agreement and any related agreements, unless the circumstances giving rise to or in connection with the Dispute are such that a Party has reasonably formed the view that continuing to perform that Party's obligations under this Agreement would cause, or be likely to cause, a risk to the health and safety of Patients or Personnel of the HSP.
	5. Nothing in this **clause 17** will prevent a Party from seeking injunctive relief where damages may be an inadequate or inappropriate remedy.
9. **INDEMNITY**
	1. Other than in respect of a negligent act, error or omission of the HSP, or its Personnel, including, if established by the HSP, the Reviewing HREC, to the extent permitted by law, in no circumstances is the HSP liable to the Institute in contract, tort or otherwise, and whatever the cause, to compensate the Institute for any special, indirect or consequential loss or damage of any nature arising from the use of the Premises, Designated Research Areas or Facilities by the Institute or the Institute’s Personnel.
	2. Each Party will release, assume and bear all liability for and indemnify and keep indemnified and defend the other Party, including all of the other Party’s Personnel, which for the HSP includes the Minister for Health and the State, from and against all actions, proceedings, suits, claims, demands, losses, damage and expenses incurred as a result of the negligence or wrongful act or omission of the first mentioned Party (“**Claims**”) which have been or which are, might or could be brought or made against or maintained or suffered or incurred by the other Party arising from or in connection with or relating to this Agreement including, without limitation, all Claims for in respect of:
		1. bodily injury to or death of or illness to any person or persons;
		2. loss or destruction of or damage to any property real or personal; and
		3. any absolute or strict liability of the Party pursuant to statute, operation of law or otherwise,

except to the extent that the liability is caused by the negligence or wrongful act or omission of the other Party or its Personnel, or where the first mentioned Party is acting under directions given by the other Party.

* 1. Each Party must maintain such insurances as are necessary to provide indemnity to it in relation to any liability which it may incur in performing its obligations under this Agreement.
1. **OTHER FACILITIES**
	1. Access by Research Staff to any conference room space, areas for discussion, areas for interviewing or deskwork, will be made available by the HSP, where possible, according to usual procedures at the Premises.
	2. Subject to the applicable Policies, Research Staff may have access to the HSP’s libraries, other resource material, and lectures or presentations on the Premises.
	3. The terms and conditions on which the Research Staff may borrow items or material from the HSP’s libraries, or from the HSP generally, shall be as specified by the HSP.
2. **TERM AND TERMINATION**
	1. Subject to amendment or earlier termination in accordance with this **clause 20**, this Agreement shall continue in force from the date of execution for such period as the Institute requires access to the Premises to conduct the Research.
	2. This Agreement may be terminated by mutual agreement of the Parties in writing.
	3. Either Party may terminate this Agreement upon 6 months’ written notice to the other Party.
	4. The HSP may terminate the Research immediately by giving written notice if the Principal Investigator is a member of the Institute’s Personnel and leaves the Institute or ceases to be available and an acceptable replacement cannot be found in accordance with **clause 9.4(c)**.
	5. In addition to **clauses 9.9** and **20.6**, the HSP may terminate the Research immediately by giving written notice to the Institute if it believes on reasonable grounds that:
3. continuing the Research poses an unacceptable risk to the rights, interests, safety or well-being of Research Participants or Patients; and
4. terminating the Research is the most appropriate way to respond to that risk.
	1. Either Party may immediately terminate this Agreement by giving notice in writing to the other Party if that other Party breaches any term of this Agreement and:
5. the breach is incapable of remedy; or
6. if the breach is remediable, it continues for a period of 30 days after written notice requiring the breach to be remedied has been given to the Party in breach.
	1. In the event of early termination of the Agreement, the Parties will take all appropriate action to close out the affected Research in a timely manner.
	2. The following provisions survive the termination of this Agreement, **clauses 1, 2, 9.6, 9.8, 12, 13, 14, 15, 17, 18, 20, 21, 23** and **24**.
7. **VARIATIONS AND REVIEW**
	1. No variations of this Agreement are legally binding on either Party unless evidenced in writing and signed by both Parties.
	2. The terms of this Agreement will be reviewed every 5 years or at other times by mutual agreement of the Parties.
	3. Variations to the Agreement as agreed by the Parties under **clause 21.1**, or where, following a review conducted in accordance with **clause 21.2** changes to the Agreement are agreed by the Parties, those changes will be set out as “Schedule 2 Special Conditions" to this Agreement (or otherwise sequentially numbered according to the sequence of the review) and signed by the authorised representatives of the Parties.
8. **WAIVER**
	1. 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.
	2. 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.
9. **NOTICES**
	1. The addresses of the Parties for the purposes of giving any notice are set out on the front page of this Agreement.
	2. A notice, consent, approval or other communication (each a notice) under this Agreement must be:
10. delivered to the Party’s address;
11. sent by pre-paid mail to the Party’s address; or
12. transmitted by email to the Party’s address.
	1. A notice given by a Party in accordance with this **clause** **23** is treated as having been given and received:
13. if delivered to a Party’s address, on the day of delivery if a business day, otherwise on the next business day; or
14. if sent by pre-paid mail, on the fifth business day after posting; or
15. if sent electronically, the date and time of delivery will be when the Party’s server or mail box has confirmed that the notice has been sent or otherwise delivered.
	1. The notice must be in readable form and capable of being reproduced on paper.
16. **GENERAL**
	1. This Agreement shall be read and construed according to the laws of the State of Western Australia and the Parties hereby submit to the exclusive jurisdiction of that State.
	2. If any provision of this Agreement is held by a court to be unlawful, invalid, unenforceable or in conflict with any rule of law, statute, ordinance or regulation the validity and enforceability of the remaining provisions shall not be thereby affected.
	3. All stamp duties and governmental charges arising out of or incidental to this Agreement shall be the responsibility of and payable by the relevant Party.
	4. The Institute’s Personnel are supernumerary to the HSP’s Personnel at the Premises.
	5. 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.
	6. Each Party shall execute such agreements, deeds and documents and do or cause to be executed or done, all such acts and things as shall be necessary to give effect to this Agreement.
	7. Neither Party may assign or sub-contract its rights and obligations under this Agreement, unless approved in writing by the other Party, such approval not to be unreasonably withheld.
	8. 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.
	9. This Agreement may be executed in any number of counterparts. All of such counterparts taken together are deemed to constitute the same Agreement.
	10. The HSP may act through the HSP's Personnel.
17. **EXECUTION**

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

SIGNED FOR AND ON BEHALF OF

**name of Health Service Provider**

in accordance with Section 41 of the *Health Services Act 2016*

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: Chief Executive

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

SIGNED FOR AND ON BEHALF OF

**name of Institute**

by its duly authorised signatory

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**SCHEDULE 1 – MANAGEMENT OF THE RESEARCH AT THE PREMISES**

**Liaison (clause 3.1)**

[*Institute to insert the details of the administrative area or section responsible for managing Research at the Premises*]

**Institute Liaison**

Position:

Address:

Email:

[*HSP to insert the details of the administrative area or section responsible for managing Research at the Premises*]

**The HSP Liaison Officer**

Position:

Address:

Email:

**SCHEDULE 2 - SPECIAL CONDITIONS**

**SCHEDULE 3 – ACCESS DETAILS**

**Item 1 – Public Hospital** **under the control of the HSP for which access is being granted:**

[insert description]

**Item 2 – Designated Research Area**

[insert description]

**Item 3 – Facilities**

[insert description]

**Item 4 – Other areas of the HSP**

[insert description]

**Item 5**

I approve [name of research staff] to access and use the Designated Research Areas at item 2 of this Schedule, Facilities at item 3 of this Schedule and other areas at item 4 of this Schedule, as applicable, for Research.

Signed [x], [job title] HSP Liaison Officer

**Item 6**

I approve [name of research staff] to access and use the other areas specified at item 4 of this Schedule for Research.

Signed [x], [job title] Head of Department