**Material and Data Transfer Agreement**

**This agreement is made between:**

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

|  |  |
| --- | --- |
| Agreement Details | *Refer to Schedule 1* |
| Health Service ref name/No: |  |
| Date of Execution: |  |

**and the parties agree as follows:**

**Background**

The Recipient has requested that the Health Service provide the Material and Data to the Recipient for the Project. The Health Service has agreed to provide the Material and Data to the Recipient and the Recipient accepts the Material and Data on the terms set out in this agreement.

**Operative Provisions**

1. **DEFINITIONS AND INTERPRETATION** 
   1. In this agreement:

**Approval** means any approval, consent, exemption, licence, permit or regulation however described, of an Authority or otherwise required by law, and any renewal of them, and includes any ethics approval.

**Authorised Personnel** has the meaning given in Item A5, Schedule 1.

**Authority** means any government or any governmental, semi-governmental, administrative, fiscal, judicial or quasi-judicial body, department, commission, authority, tribunal, Minister of the Crown, Ministerial Body, agency, entity or Parliament.

**Commencement Date** has the meaning given in Item A1, Schedule 1.

**Data** has the meaning given in Item C1, Schedule 1.

**End Date** has the meaning given in Item A1, Schedule 1.

**Fee** has the meaning given in Schedule 2.

**GST** has the meaning given in the GST Law.

**GST Law** has the meaning given in *A New Tax System (Goods and Services Tax) Act 1999* (Cth).

**Intellectual Property** means all present and future industrial and intellectual property rights, including:

### inventions, patents, copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trademarks, database rights, know how, trade secrets and the right to have confidential information kept confidential, and any and all other rights to intellectual property which may subsist anywhere in the world; and

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

**Location** has the meaning given in Item A4, Schedule 1.

**Material** means the materials specified in Item B1, Schedule 1, and includes any Modification.

**Modification** means any progeny, modification or improvements to the Material that the Recipient develops, directly or indirectly, while using the Material provided by the Health Service.

**Project** has the meaning given in Item A2, Schedule 1

**Publication** means any disclosure which results from, or references, the Material or Data, whether in written, oral, electronic or any other form, including any article, manuscript, abstract, report, paper, presentation, slides and internet post.

**Purpose** has the meaning given in Item A3, Schedule 1.

**Responsible HREC** has the meaning given in Item A6, Schedule 1.

**Special Conditions** mean the special conditions in Schedule 1.

* 1. In this agreement, unless the context otherwise requires:
     1. references to a person include an individual, a body politic, the estate of an individual, a firm, a corporation, an authority, an association or joint venture (whether incorporated or unincorporated), or a partnership;
     2. the words “including”, “includes” and “include” will be read as if followed by the words “without limitation”;
     3. reference to a “party” is to a party to this agreement;
     4. words in the singular include the plural (and vice versa) and words denoting any gender include all genders;
     5. if a word or phrase is defined, any other part of speech or grammatical form of that word or phrase has a corresponding meaning;
     6. reference to any legislation or to any section or provision of it includes any statutory modification or re-enactment of, or any statutory provision substituted for, that legislation, section or provision;
     7. no rules of construction apply to the disadvantage of a party because that party was responsible for the drafting of this agreement or of any of the provisions of this agreement;
     8. headings are for convenience only and do not affect interpretation or construction; and
     9. reference to “$” is to Australian currency.

1. **TERM**

This agreement commences on the Commencement Date and, subject to earlier termination in accordance with clause 13, expires on the End Date.

1. **NON-EXCLUSIVE SUPPLY OF MATERIAL AND DATA**
   1. The Health Service will provide the Data to the Recipient.
   2. Unless the Health Service otherwise agrees, the Recipient must (at the Recipient's cost) collect the Material from the Health Service premises identified by the Health Service.
   3. On receipt or collection of the Material (as applicable), risk in the Material transfers to the Recipient.
   4. If the Recipient, its employees or anyone authorised by the Recipient enters the premises of the Health Service (or of any other agency of the State of Western Australia) in connection with this agreement, the Recipient must and must ensure that such persons:
      1. promptly comply with all policies and directions of the Health Service (or such applicable State agency) or its employees or agents in respect of access, health, safety and security; and
      2. wear identification badges, clearly identifying them as the Service Recipient’s Personnel.
   5. Nothing in this agreement provides the Recipient with exclusive rights to the Material or Data. The Health Service may in its discretion use and exploit the Material and Data and sell, assign, disclose, distribute, licence and supply Material and Data to third parties, including for commercial purposes.
2. **USE OF MATERIAL AND DATA** 
   1. The Recipient will:
      1. use, and ensure the use of, the Material and Data solely for the Purpose and exclusively for non-commercial purposes;
      2. use and store, and ensure the use and storage of, the Material and Data:
         1. in accordance with all applicable laws and regulations, industry standards, Approvals and the Special Conditions (if any);
         2. in accordance with the additional requirements set out in Schedule 1; and
         3. to the standards reasonably expected of a prudent, expert and experienced user of material and data such as the Material and Data; and
      3. retain the Material and Data only at the Location;
      4. ensure that the Material and Data are only used under the direct supervision of the Principal Investigator or those Authorised Personnel identified in Schedule 1 as supervisory Authorised Personnel,

unless (and to the extent) otherwise required by law, or in accordance with the prior written consent of the Health Service.

* 1. Where the Data includes information that is not personal information, the Recipient must not modify or use it, or link it to other information, in a way that identifies, or might lead to the identification of an individual to whom it relates unless authorised to do so. The Recipient acknowledges that a breach of this clause may constitute an offence under the Health Services Act 2016.
  2. The Recipient must, at its cost, on the earlier of:
     1. expiry or termination of this agreement;
     2. within 30 days of receipt of a request from the Health Service; or
     3. when the Project for which the Material and Data were supplied discontinues or there is no further need for the Data and Materials in connection with the Project,

return to the Health Service or, at the Health Service's request, destroy the Data and all remaining or unused Material, except to the extent retention of Data or Material is required by law. The Recipient will use all reasonable efforts to ensure that such return or destruction is completed within 30 days.

1. **PROVISION OF MATERIAL AND DATA TO THIRD PARTIES**
   1. The Recipient must not:
      1. disclose the Data to any person other than the Authorised Personnel;
      2. allow any person, other than the Authorised Personnel, access to the Material or Data; or
      3. transfer, sell, licence or provide the Material or Data to any other person,

unless (and to the extent) otherwise required by law, or in accordance with the prior written consent of the Health Service.

* 1. If the Health Service consents to the disclosure of Data or provision of Material to a third party:
     1. the Recipient must make the disclosure, and provide the Material, in accordance with any conditions imposed by the Health Service on its consent;
     2. the Recipient remains responsible for all Data and Material provided to the third party and is not relieved of its obligations under this agreement and will be liable for all acts and omissions of the third party in respect of the Data and Material ;
     3. the Recipient must, prior to disclosure of any Data or provision of any Material, ensure that the third party has executed an agreement on terms which:
        1. give effect to, and are no less restrictive than, the terms of this agreement; and
        2. are otherwise acceptable to the Health Service in its sole discretion,

and allow the Health Service the reasonable opportunity to review and amend the terms of the agreement prior to its execution;

* + 1. in respect of any agreement contemplated by clause 5.2.3 the Recipient must, prior to giving any consent or approval under the agreement, obtain the approval of the Health Service and comply with any conditions imposed on that approval; and
    2. if clause 4.3 applies, the Recipient must promptly ensure the return or (if requested by the Health Service) destruction of the Data and all remaining or unused Material provided to the third party.

1. **PROPERTY AND INTELLECTUAL PROPERTY**
   1. The Data is the property of the Health Service. The Material is the property of the Health Service, except to the extent that property rights in the Material cannot be held by the Health Service, in which case that Material is under the custodianship of the Health Service.
   2. The Health Service:
      1. owns all Intellectual Property in the Material (excluding any Modification) and the Data; and
      2. will, subject to any Special Condition in Item B5 of Schedule 1 to the contrary, own all Intellectual Property in any Modification, and the Recipient (and its officers and employees) automatically assign the entire future Intellectual Property in all Modifications to the Health Service upon their creation.
   3. The Health Service grants the Recipient a royalty free, non-exclusive, non-transferable and non sub-licenseable (without the Health Service's prior consent) right to use the Material and Data for the Purpose on the terms and conditions of this agreement.
   4. The Recipient acknowledges that the Material and Data is or may be the subject of a patent or patent application. Except as provided in this agreement, the Recipient agrees that it has no express or implied licence or other right to any patents, patent applications, trade secrets or other proprietary rights of the Health Service. In particular, no express or implied licence or other right is provided to use the Material or Data for commercial purposes.
2. **RECORDS AND INSPECTION**
   1. The Recipient must keep and maintain, for not less than 7 years, all records in whatever form that relate to the use of the Data and Material in accordance with (as applicable having regard to the nature of the record) good accounting practices or good record keeping practices, standards and procedures. The Recipient must make those records available for inspection by the Health Service as reasonably required by the Health Service.
   2. The Health Service has the right, on notice to the Recipient, to inspect the Recipient's premises to confirm compliance with the requirements of this agreement.
   3. The Recipient must at its cost provide all appropriate resources and assistance to the Health Service, its employees, agents and contractors in accessing records or inspecting premises as contemplated by this clause.
3. **CONFIDENTIALITY**
   1. The Recipient must:
      1. treat as confidential information any Material, Data or other information provided by the Health Service; and
      2. take all reasonable and necessary precautions to restrict access to researchers who are directly involved in the Purpose and who are placed under an obligation to observe the terms of this agreement.
   2. These obligations of confidentiality do not apply to information which:
      1. was lawfully in the Recipient’s possession or control prior to the date of disclosure;
      2. was in the public domain or enters into the public domain through no improper act on the Recipient’s part or on the part of any of the Recipient’s employees;
      3. is given to the Recipient from sources independent of the Health Service;
      4. was independently developed by the Recipient without the knowledge of the information provided by the Health Service as evidenced by contemporaneous written records; or
      5. must be disclosed for minimum lawful compliance with court orders, regulations or statutes.
   3. The Recipient will immediately notify the Health Service if it becomes aware that disclosure of any information covered by this clause 7 is, or may be required by law, and will provide all reasonable assistance and co-operation which the Health Service reasonably considers necessary for the purpose of enabling the Health Service to seek a protective order or other relief from disclosure.
   4. The Recipient’s obligations of confidentiality will survive termination of this agreement and will continue until the confidential information disclosed by the Health Service lawfully becomes part of the public domain.
4. **PRIVACY**

The Recipient will comply with the *Privacy Act 1988* (Cth), the Australian Privacy Principles and any other laws, codes or guidelines which apply in the jurisdiction in which the Material and Data is to be located and which relates to the use, collection, storage or disclosure of any personal and/or health information.

1. **INSURANCE, LIABILITY AND INDEMNITY**
   1. The Recipient must take out and maintain for the term of this agreement, with reputable and solvent insurers:
      1. which carry on insurance business in Australia and are authorised in Australia to operate as insurance companies; or
      2. which are otherwise approved by the Health Service,

such insurance as the Health Service determines (in its discretion) is reasonable against any risk or liability arising out of or in connection with this agreement.

* 1. The Recipient must, on request from time to time, provide proof of the insurances required by this clause including sufficient evidence of the terms of such insurance and a certificate of currency.
  2. The Recipient:
     1. acknowledges that it will use the Material and Data at its own risk; and
     2. accepts sole responsibility and liability for the conduct of the Project.
  3. The Health Service:
     1. to the fullest extent permitted by law, excludes all warranties, express or implied, including any warranties of merchantability or fitness for a particular purpose; and
     2. makes no representations and gives no warranties that the Material and Data will not infringe a third party's Intellectual Property rights.
  4. The Recipient agrees to indemnify and keep indemnified the State of Western Australia, the Minister for Health, the Health Service and its officers, employees, agents and representatives against any and all damages, expenses (including legal expenses), claims, demands, suits or other liability arising from or in connection with:
     1. the Recipient’s use, transport, storage, or disposal of the Material and Data;
     2. the conduct of the Project; and
     3. breach of law, breach of this agreement, negligence or wilful default by the Recipient, its officers, employees, agents and representatives,

except to the extent that such damage or liability is due to the negligence or wilful misconduct of the Health Service or its officers, employees, agents or representatives.

* 1. Notwithstanding any other provision of this agreement, the Health Service and its officers, employees, agents and representatives have no liability to the Recipient for any indirect or consequential loss, including any loss of profit, loss of opportunity, loss of goodwill or business reputation or other similar pure economic loss arising out of or in relation to this agreement.
  2. Part 1F of the *Civil Liability Act 2002* (WA) does not apply to this agreement.

1. **PUBLICATIONS AND PUBLICITY** 
   1. The Recipient must, and must ensure that the Authorised Personnel and any third party approved under clause 5:
      1. provide the Health Service with all Publications at least 30 days prior to submission for publication or other disclosure;
      2. amend any Publication as required by the Health Service to preserve the confidentiality of the Health Service's Data and information;
      3. provide the Health Service with copies of any reports and an outline of results and any discoveries in relation to the use of the Material and Data, using reasonable endeavours to provide such information within 30 Days of completion of the Project; and
      4. in any Publication, acknowledge:
         1. the source of the Material and Data and appropriately cite the Health Service;
         2. where required by the Australian Code for the Responsible Conduct of Research (as amended from time to time), staff members of the Health Service; and
         3. authorship and any other matters if, and to the extent, specified in the Special Conditions.
   2. The Recipient must not use:
      1. this agreement or the Health Service's name or logo;
      2. the name or logo of any person specified in this agreement or the State of Western Australia,

in any publication, advertisement or media release, or for any other promotional purposes, without the prior written consent of the Health Service and in accordance with the terms and conditions imposed by the Health Service.

1. **FEE, PAYMENTS AND GST**
   1. In consideration for the Health Service providing the Materials and Data to the Recipient, the Recipient will pay the Fee to the Health Service in accordance with the payment terms in Schedule 2.
   2. The Fee is exclusive of GST and subject to this clause. In this clause, capitalised terms not defined in this agreement have the meaning given in the GST Law.
   3. In addition to any other payment obligation of the Recipient for a Supply in connection with this agreement, at the time of payment, the Recipient must pay to the Health Service (or reimburse the Health Service) for any GST that the Health Service is required to pay on any Supply made by the Health Service in connection with this agreement, in accordance with GST Law.
   4. Payments are subject to either receipt of a valid Tax Invoice or a Recipient Created Tax Invoice.
   5. The Recipient and the Health Service each warrant that they are registered under GST Law.
2. **TERMINATION**
   1. Either party may terminate this agreement:
      1. at any time by giving 45 days’ written notice to the other party; or
      2. if the other party is in breach of any of its obligations under this agreement and, if that breach is capable of remedy, does not rectify that breach within 30 days after receipt of a notice to remedy that breach.
   2. The expiry or termination of this agreement is without prejudice to any accrued rights of either party as at the date of expiry or termination.
3. **NOTICES**
   1. A notice, consent, approval or other communication under this agreement (*Notice*):
      1. is only effective if it is in writing and signed by the sender or a person duly authorised by the sender;
      2. must be delivered to the intended recipient by prepaid post (or if posted to an address in another country, by registered airmail), hand, facsimile or email (provided the size of the email is less than 10MB) to the address, fax number or email address on the front of this agreement or the address, fax number or email address last notified by the intended recipient to the sender;
   2. A Notice it is taken to have been received, in respect of delivery:
      1. in person, when delivered;
      2. by post, 3 business days after the date of posting (if posted to an address within Australian) and 5 business days if posted to an address in another country;
      3. by fax, on receipt by the sender of advice from the sending machine that the transmission was sent without error in its entirety to the correct facsimile address; or
      4. by email, the earlier of the time the sender receives an automated message from the intended recipient's information system confirming delivery of the email and 24 hours after the time the email is sent (as recorded on the device from which the sender sent the email), unless the sender receives, within that 24 hour period, an automated message that the email has not been received.
   3. If a notice is taken to be received on a non-business day or after 5:00pm, it is taken to have been received at 9:00am on the next business day.
4. **GENERAL** 
   1. (**Survival**) Without limiting any other term of this agreement, this clause 15 and clauses 1, 4, 5.2, 6, 7, 8, 9, 10 and 11 survive termination or expiry of this agreement*.*
   2. (**Disputes**) The parties will attempt in good faith to resolve through negotiation any disputes arising out of or relating to this agreement.
   3. (**Waiver**) Any failure to exercise or enforce, delay in exercising or enforcing or partial exercise or enforcement of a right, power or remedy under any law or this agreement by a party does not operate as a waiver or estoppel of the exercise or enforcement or further exercise or enforcement of that or any other right, power or remedy under any law or this agreement.
   4. (**Assignment**) Subject to clause 15.5, a party must not assign, transfer or novate this agreement or any of its rights, benefits or obligations under the agreement without the prior written consent of the other party, and on such terms and conditions as are determined by the other party.
   5. (**Health Service assignment**) The Health Service may assign or novate this agreement to any agent of the State of Western Australia that is taking over the Health Service's role in respect of the Material and Data, and will notify the Recipient of such change.
   6. (**Relationship**) Nothing in this agreement will be construed so as to make any party an employee, agent or partner of another, or create any relationship of partnership, agency, or trust whatsoever.
   7. (**Amendment**) This agreement may only be amended in writing, signed by the parties.
   8. (**Severability**) If any provision of this agreement is invalid or unenforceable, it will be deemed deleted but the remaining provisions of this agreement will remain in full force and effect.
   9. (**Entire agreement**) This agreement contains the entire understanding between the parties concerning its subject matter and supersedes all prior communications between the parties.
   10. (**Authorisation**) Each party represents and warrants to the other that it has full power to enter into and perform its obligations under this agreement and that when executed this agreement will constitute legal, valid, and binding obligations under its terms.
   11. (**Further action**) Each party will execute all documents and perform all acts necessary to give full effect to this agreement.
   12. (**Counterparts**) This agreement may be signed in any number of counterparts.
   13. (**Governing law and jurisdiction**) This agreement is governed by the law in force in the State of Western Australia. The parties irrevocably submit to the exclusive jurisdiction of the courts exercising jurisdiction in Western Australia, and any court that may hear appeals from any of those courts, for any proceeding in connection with this agreement, subject only to the right to enforce a judgment obtained in any of those courts in any other jurisdiction.

Executed as an agreement by:

Signed for and on behalf of the

[**insert name of Health Service**]

in accordance with section 41 of the *Health Services Act* *2016* (WA)by:

Signed: ………………………………….

Name: …………………………………..

Position: …………………………………

Date: ………………………………….

Signed for and on behalf of the **Recipient** by its duly authorised representative who declares that he or she has no notice of revocation or suspension of his or her authority:

Signed: ………………………………….

Name: …………………………………...

Position: …………………………………

Date: ………………………………….

Read, understood and acknowledged by the **Principal Investigator / Recipient Scientist**

Signed: ………………………………….

Name: ………………………………….

Position: …………………………………

Date: ………………………………….

**SCHEDULE 1 DETAILS**

**Part A – Agreement Details**

|  |  |  |
| --- | --- | --- |
| Item A1 | **Commencement Date:** | *Insert* |
| **End Date:** | *Insert* |
| Item A2 | **Project** (title): | *Insert* |
| Item A3 | **Purpose:** | [***Note to Health Service – under clause 4 above, the use of the Material and Data is limited to "the Purpose" and for non-commercial purposes. Please consider this in detailing the Purpose here – examples below. Note ability to include further restrictions on use under Items B and C below***.]  [*The purpose of the Project, including internal non-commercial biomedical research purposes in connection with the Project, but excluding use of the Material or Data:*   1. *for any products or for the generation of other products or processes for profit-making or commercial purposes;* 2. *for any human in vivo use whatsoever or any human in vitro diagnostic or therapeutic applications;* 3. *which is not strictly in accordance with [reference any other document, protocol, research plan etc];* 4. *contrary to the Recipient's current HREC approval;* 5. *to export Material from Australia or store Material in a biobank;* 6. *to create a product for human use or consumption*;]   [***Note to Health Service – if considering including a commercial purpose (overriding clause 4 above) consider whether further intellectual property and other terms are required and seek legal advice on the drafting of those terms***.] |
| Item A4 | **Location** (where Material and Data to be stored by Recipient): | *Insert* |
| Item A5 | **Authorised Personnel** | **Requester (if applicable)**  name:  position:  work location:  contact details:  **Principal Investigator (if different to Requester / if applicable)**  name:  position:  work location:  contact details:  **Other Authorised Personnel (Material and Data)** *[Note, specify if only Material or only Data]*  *[list all persons having access to the Material / Data. If the Principal Investigator is not the person required to have direct supervision over use of the Material and Data, state which Authorised Personnel are supervisory within the meaning of clause 4.1.4]* |
| Item A6 | **Responsible HREC:** | *Insert* |
| Item A7 | **Details of Approved Protocol** | version approved by HREC |

**Part B – Material Details**

|  |  |  |
| --- | --- | --- |
| Item B1 | **Material** | *Material to be listed, e.g. bio specimens- tissue, blood and blood products, fluids, including cerebro spinal fluid, breast milk, peritoneal dialysis, urine, nasal swab* |
| Item B2 | **Material security** | *Recipient to provide details of how the Material will be stored securely* |
| Item B3 | **Additional restrictions on use of Material** (circle) | [Yes] [No] |
| **If yes, provide details** | *Health Service to detail (for example: “to be used only for non-clinical research”; "not to be used in the treatment or diagnosis of humans”)* |
| Item B4 | **Will Material be shared by Recipient with third parties? (circle)** | [Yes] [No] |
| **If yes, provide details** | *Insert* |
| **If yes, has Health Service provided prior written consent for Recipient to share Material?** (circle) | [Yes] [No] |
| **Details of how the Material will be disseminated to third parties** | *Insert* |
| Item B5 | Additional Special Conditions for Materials | *[Health Service to consider any other special conditions for Materials – examples below.]*  *[DNA/RNA testing of Materials is not permitted.]*  *[Institutional Biosafety Committee oversight is required in respect of [insert] (e.g. re Covid positive/infectious samples)]*  *[If the Recipient is to own Intellectual Property in any Modifications, those Modifications need to be specified here (see clause 6.3) e.g: The Recipient will own all Intellectual Property in [insert type/s of modification]. The Recipient does not assign future Intellectual Property in such modifications to the Health Service and the Health Service does not grant the Recipient any right to use such modifications. Consider whether the Health Service should receive a licence to use such modifications.]* |

**Part C – Data Details**

|  |  |  |
| --- | --- | --- |
| Item C1 | **Data:** | *Insert* |
| Item C2 | **Data format**  (circle) | (i)non-identifiable [Yes] [No]  (ii)re- identifiable [Yes] [No]  (iii)individually identifiable [Yes] [No]  if ‘yes’ to (iii) please provide reason why individual’s identity is required.  add attachment if more space required |
| Item C3 | **Data source/collection**(s) from which the Data will be sourced (if known) | *Insert* |
| **Is Data Custodian(s) approval required?** (circle) | **[Yes] [No]**  *If yes, Data Custodian(s) to name, sign and date* |
| Item C4 | **Data Security** | *Recipient to provide details of how the Data will be stored securely* |
| Item C5 | **Additional restrictions on use of Data** (circle) | **[Yes] [No]** |
| **If yes, provide details** | *Health Service to detail (for example: “to be used only for non-clinical research”; "not to be used in the treatment or diagnosis of humans”)* |
| Item C6 | **Will Data be shared by Recipient with third parties?** (circle) | **[Yes] [No]** |
| **If yes, provide details** | *Insert* |
| **If yes, has Health Service provided prior written consent for Recipient to share Data?** (circle) | **[Yes] [No]** |
| Details of how the Data will be disseminated to third parties | *Insert* |

**Part D – Special Conditions**

|  |  |  |
| --- | --- | --- |
| Item D1 | **Special Conditions** | *[****Health Service to specify or insert "NOT USED****"]* |
| *[Example special condition - Retention and Destruction*  *Detail any relevant retention periods, e.g. archive for 15 years for clinical trials as per NHMRC TGA requirements.*  *Detail any change to the position in clause 4.3 (that Material and Data must be returned or (if HSP requires) destroyed on expiry/termination, if HSP requests or when the Project ends].* |
| *[Example special condition - Publication rights*  *Detail any Publication rights in addition to the rights in clause 11.2 (to cite the Health Service as the source of the Material and Data and comply with the Australian Code for the Responsible Conduct of Research in acknowledging Health Service staff members). For example, state whether authorship must be acknowledged]* |
|  |
|  |

**SCHEDULE 2 – PAYMENT SCHEDULE**

**Fee**

|  |  |
| --- | --- |
| **Description of milestone / event** | **Fee for Milestone in AUD (ex GST)** |
| *[****Health Service to insert payment milestones (e.g. delivery of particular data or materials) or insert N/A]****]* | $ *[****Health Service to insert amount/s or N/A****]* |
|  | $ |
|  | $ |
|  | $ |
|  | $ |
|  | $ |
|  | $ |

*[****If the fees are to be paid over a number of years or otherwise justify escalation or variation for increased costs, consider including the following provisions:*** *The amounts of the Fees set out in the table above are subject to escalation and variation in accordance with the following terms:*

*(a) On the first anniversary of the Commencement Date, and on each anniversary thereafter during the term of this agreement, each amount will be increased in accordance with movements in the CPI Index over the preceding 12-month period. For the purposes of this clause, "CPI Index" means the Consumer Price Index, Health Group, for Perth last published by the Australian Bureau of Statistics before the relevant date.*

*(b) Without limiting paragraph (a) above, the amounts of the Fees may be varied by the Health Service, acting reasonably, to take into account any increase in the volume or cost of consumables used providing the Material or Data or increases in the Health Service’s capital user charges or staffing costs associated with providing the Material or Data. Any resultant changes will take effect forty-five (45) days after the Health Service notifies the Recipient of that increase. If the Recipient disputes the amount of an increase, the dispute will be referred for resolution pursuant to clause 15.2.****]***

**Payment terms** *[****Health Service to amend as required****]*

|  |  |
| --- | --- |
| **1** | The Recipient will pay to the Health Service the amount of the Fee specified for a milestone or event above within 30 days of the occurrence of the milestone or event. |
| **2** | The Recipient will pay the Fee into the following bank account:  [***Health Service to insert bank details***] |
| **3** | The Recipient may withhold payment of any amount of the Fee which it disputes in good faith is payable due to the Data for the disputed amount not meeting the criteria specified in the [insert]. |
| **4** | No payments will be made to the Health Service until:   1. This agreement has been executed 2. All regulatory documents have been submitted to [insert] 3. HREC approval |

**[Note: The following terms are an example of terms that would meet the minimum requirements of clause 5.2.3 for a third party receiving Data or Material from the Recipient. These terms should be removed before this document is provided to the Recipient, and only provided once they have been adapted for the requirements of the Project, Data and Material.]**

**Example minimum terms to be entered into by a third party consented to by the Health Service under MDTA clause 5.2**

This agreement is entered into on [*insert date*] by:

[*insert details*] (**Original Recipient**); and

[*insert details*] (**Approved Third Party / ATP**).

**BACKGROUND**

A The Recipient and Health Service are parties to the MDTA.

B Under the MDTA, the Recipient is only permitted to provide the Material or Data to a third party with the prior consent of the Health Service and subject to the terms and conditions required by the Health Service. The Health Service has required entry into these terms and conditions as a precondition to the ATP being provided with the Material and Data.

**OPERATIVE PART**

1. (**Term**) This agreement commences on the Start Date and subject to earlier termination in accordance with clause 19, expires on the Expiry Date.
2. (**Provision of Data and Material**) The Recipient will provide the Data to the ATP. The Material will be provided or available for collection in accordance with the Schedule.
3. (**Risk in Material**) On collection or receipt (as applicable), risk in the Material transfers to the ATP.
4. (**Non-exclusive**) Nothing in this agreement provides the ATP with exclusive rights to the Material or Data.
5. (**No** **additional third parties**) The ATP must not:
   * 1. disclose the Data to any person other than the Recipient and the Authorised Personnel;
     2. allow any person, other than the Recipient and Authorised Personnel, access to the Material or Data; or
     3. transfer, sell, licence or provide the Material or Data to any other person,

unless (and to the extent) otherwise required by law.

1. (**Use**) The ATP will (unless, and only to the extent, otherwise required by law):
   * 1. use, and ensure the use of, the Material and Data solely for the Purpose and exclusively for non-commercial purposes;
     2. use and store, and ensure the use and storage of, the Material and Data:
        1. in accordance with all applicable laws and regulations, industry standards, Approvals and the requirements in the Schedule;
        2. in accordance with the additional requirements set out in the Schedule; and
        3. to the standards reasonably expected of a prudent, expert and experienced user of material and data such as the Material and Data; and
     3. retain the Material and Data only at the ATP Location; and
     4. ensure that the Material and Data are only used under the direct supervision of the Authorised Personnel identified in the Schedule as supervisory Authorised Personnel.
2. (**Identifying Data**) Where the Data includes information that is not personal information, the ATP must not modify or use it, or link it to other information, in a way that identifies, or might lead to the identification of an individual to whom it relates unless authorised to do so. The ATP acknowledges that a breach of this clause may constitute an offence under the *Health Services Act 2016* (WA).
3. (**Return or destruction**) The ATP must, at its cost, on the earlier of:
   * 1. expiry or termination of this agreement;
     2. within 20 days of receipt of a request from the Recipient or the Health Service; or
     3. when the Project for which the Material and Data were supplied discontinues or there is no further need for the Data and Materials in connection with the Project,

return to the Recipient or, at the Recipient's request, destroy the Data and all remaining or unused Material, except to the extent retention of Data or Material is required by law. The Recipient will use all reasonable efforts to ensure that such return or destruction is completed within 20 days.

1. (**Property and** **Intellectual Property**)
   1. (*Property*) The ATP acknowledges that the Data is the property of the Health Service and the Material is the property of the Health Service, except to the extent that property rights in the Material cannot be held by the Health Service, in which case that Material is under the custodianship of the Health Service.
   2. (*Data and Material*) The ATP acknowledges that the Health Service owns all Intellectual Property in the Material (excluding any Modification) and the Data.
   3. (*Modifications*):
      1. **[Option 1: Health Service owns IP in Modifications]**: [*If the MDTA provides that the Health Service owns Intellectual Property in Modifications, the ATP must assign future Intellectual Property in all Modifications to the Health Service upon their creation. A separate agreement between the ATP and Health Service will be required to effect that assignment*.]
      2. **[Option 2: Recipient or ATP owns IP in Modifications]**: [*Recipient may insert a clause, provided it does not detract from any other provision of this agreement*.]
   4. (*Licence*) The Recipient grants the ATP a non-exclusive, non-transferable, non sub-licenseable right to use the Material and Data for the Purpose on the terms and conditions of this agreement.
   5. (*Patents*) The ATP acknowledges that the Material and Data is or may be the subject of a patent or patent application. Except as provided in this agreement, the ATP agrees that it has no express or implied licence or other right to any patents, patent applications, trade secrets or other proprietary rights of the Health Service. In particular, no express or implied licence or other right is provided to use the Material or Data for commercial purposes.
2. (**Records and premises**) The ATP must:
   * 1. keep and maintain, for not less than 7 years, all records in whatever form that relate to the use of the Data and Material in accordance with (as applicable having regard to the nature of the record) good accounting practices or good record keeping practices, standards and procedures;
     2. make those records available for inspection by the Recipient and the Health Service as reasonably required;
     3. provide the Recipient and Health Service with access to inspect the ATP's premises to confirm compliance with the requirements of this agreement; and
     4. at its cost provide all appropriate resources and assistance to the Recipient and the Health Service, its employees, agents and contractors in accessing records or inspecting premises as contemplated by this clause.
3. (**Confidentiality**)
   1. The ATP must:
      1. treat as confidential information any Material, Data or other information provided by the Recipient; and
      2. take all reasonable and necessary precautions to restrict access to researchers who are directly involved in the Purpose and who are placed under an obligation to observe the terms of this agreement.
   2. These obligations of confidentiality do not apply to information which:
      1. was lawfully in the ATP's possession or control prior to the date of disclosure;
      2. was in the public domain or enters into the public domain through no improper act on the ATP's part or on the part of any of the ATP's employees;
      3. is given to the ATP from sources independent of the Recipient and the Health Service;
      4. was independently developed by the ATP without the knowledge of the information provided by the Recipient or the Health Service as evidenced by contemporaneous written records; or
      5. must be disclosed for minimum lawful compliance with court orders, regulations or statutes.
   3. The ATP will immediately notify the Recipient if it becomes aware that disclosure of any information covered by this clause 11 is, or may be required by law, and will provide all reasonable assistance and co-operation which the Recipient or the Health Service reasonably considers necessary for the purpose of enabling the Recipient or the Health Service to seek a protective order or other relief from disclosure.
   4. The ATP's obligations of confidentiality will survive termination of this agreement and will continue until the confidential information disclosed by the Recipient and the Health Service lawfully becomes part of the public domain.
4. (**Privacy**) The ATP will comply with the *Privacy Act 1988* (Cth), the Australian Privacy Principles and any other laws, codes or guidelines which apply in the jurisdiction in which the Material and Data is to be located and which relates to the use, collection, storage or disclosure of any personal and/or health information.
5. (**Insurance**) The ATP must take out and maintain for the term of this agreement, with reputable and solvent insurers:
   * 1. which carry on insurance business in Australia and are authorised in Australia to operate as insurance companies; or
     2. which are otherwise approved by the Health Service,

such insurance as the Recipient and the Health Service determine (in its discretion) is reasonable against any risk or liability arising out of or in connection with this agreement. The ATP must, on request from time to time, provide to the Recipient and the Health Service proof of the insurances required by this clause including sufficient evidence of the terms of such insurance and a certificate of currency.

1. (**Risk and no warranty**) The ATP acknowledges that it will use the Material and Data at its own risk and accepts sole responsibility and liability for the conduct of the ATP Project. The Health Service and the Recipient:
   * 1. to the fullest extent permitted by law, exclude all warranties, express or implied, including any warranties of merchantability or fitness for a particular purpose; and
     2. make no representations and give no warranties that the Material and Data will not infringe a third party's Intellectual Property rights.
2. (**Indemnity**) The ATP agrees to indemnify and keep indemnified the Recipient, the State of Western Australia, the Minister for Health, the Health Service and its officers, employees, agents and representatives (**indemnified persons**) against any and all damages, expenses (including legal expenses), claims, demands, suits or other liability arising from or in connection with:
   * 1. the ATP's use, transport, storage, or disposal of the Material and Data;
     2. the conduct of the Project; and
     3. breach of law, breach of this agreement, negligence or wilful default by the ATP, its officers, employees, agents and representatives,

except to the extent that such damage or liability is due to the negligence or wilful misconduct of the Recipient or its officers, employees, agents or representatives or of the Health Service. The Recipient declares that it holds on trust for each of the indemnified persons the benefit of the indemnity and release given by ATP, in favour of each indemnified person. ATP acknowledges the existence of such trusts and consents to:

* + 1. the Recipient exercising rights in relation to, or otherwise enforcing, such indemnities and releases on behalf of the indemnified persons; and
    2. the indemnified persons exercising rights in relation to, or otherwise enforcing, the indemnities and releases.

Part 1F of the *Civil Liability Act 2002* (WA) does not apply to this agreement.

1. (**No consequential loss**) Notwithstanding any other provision of this agreement, the Recipient, its officers, employees, agents and representatives and the Health Service, its officers, employees, agents and representatives have no liability to the ATP for any indirect or consequential loss, including any loss of profit, loss of opportunity, loss of goodwill or business reputation or other similar pure economic loss arising out of or in relation to this agreement.
2. (**Publications**) The ATP must, and must ensure that the ATP Authorised Personnel:
   * 1. provide the Recipient with all Publications at least 30 days prior to submission for publication or other disclosure;
     2. amend any Publication as required by the Recipient to preserve the confidentiality of the Health Service's Data and information; and
     3. provide the Recipient with copies of any reports and an outline of results and any discoveries in relation to the use of the Material and Data, using reasonable endeavours to provide such information within 30 Days of completion of the Project.
     4. in any Publication, acknowledge:
        1. the source of the Material and Data and appropriately cite the Health Service;
        2. where required by the Australian Code for the Responsible Conduct of Research (as amended from time to time), staff members of the Health Service; and
        3. authorship and any other matters if, and to the extent, specified in the Special Conditions.
3. (**No publicity**) The Recipient must not use this agreement or the Health Service's name or logo or the name or logo of any person specified in this agreement or the State of Western Australia, in any publication, advertisement or media release, or for any other promotional purposes, without the prior written consent of the Recipient and in accordance with the terms and conditions imposed by the Recipient.
4. (**Termination**) This agreement will terminate immediately if the MDTA is terminated or expires. The Recipient will promptly provide notice to the ATP of the termination or expiry of the MDTA. The expiry or termination of this agreement is without prejudice to any accrued rights of either party as at the date of expiry or termination.
5. (**General**)
   1. (*survival*) Without limiting any other term of this agreement, this clause 20, clauses 21 and 22 and clauses 6 to 18 survive termination or expiry of this agreement.
   2. (*assignment*) A party must not assign, transfer or novate this agreement or any of its rights, benefits or obligations under the agreement without the prior written consent of the other party and the Health Service, and on such terms and conditions as are determined by the other party and the Health Service.
   3. (*amendment*) This agreement may only be amended in writing, signed by the parties.
   4. (*governing law and jurisdiction)* This agreement is governed by the law in force in the State of Western Australia. The parties irrevocably submit to the exclusive jurisdiction of the courts exercising jurisdiction in Western Australia, and any court that may hear appeals from any of those courts, for any proceeding in connection with this agreement, subject only to the right to enforce a judgment obtained in any of those courts in any other jurisdiction.
6. (**Definitions**) In this agreement, the terms **MDTA**, **Health Service**, **Start Date**, **Expiry Date**, **ATP Authorised Personnel**, **ATP Location**, **ATP Responsible HREC**, **ATP Project**, **ATP Purpose** and **Data** each have the meaning given to that term in the Schedule, and:

**Approval** means any approval, consent, exemption, licence, permit or regulation however described, of an Authority or otherwise required by law, and any renewal of them, and includes any ethics approval.

**Authority** means any government or any governmental, semi-governmental, administrative, fiscal, judicial or quasi-judicial body, department, commission, authority, tribunal, Minister of the Crown, Ministerial Body, agency, entity or Parliament.

**Intellectual Property** means all present and future industrial and intellectual property rights, including:

* + 1. inventions, patents, copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trademarks, database rights, know how, trade secrets and the right to have confidential information kept confidential, and any and all other rights to intellectual property which may subsist anywhere in the world; and
    2. any application for or right to apply for registration of any of those rights.

**Material** means the materials specified in the Schedule, and includes any Modification.

**Modification** means any progeny, modification or improvements to the Material that the ATP develops, directly or indirectly, while using the Material provided by the Recipient.

**Publication** means any disclosure which results from, or references, the Material or Data, whether in written, oral, electronic or any other form, including any article, manuscript, abstract, report, paper, presentation, slides and internet post.

**Schedule** means the Schedule to this agreement, which forms part of this agreement.

**Special Conditions** means the special conditions in the Schedule.

1. (**Interpretation**) In this agreement, unless the context otherwise requires:
   * 1. references to a person include an individual, a body politic, the estate of an individual, a firm, a corporation, an authority, an association or joint venture (whether incorporated or unincorporated), or a partnership;
     2. the words “including”, “includes” and “include” will be read as if followed by the words “without limitation”;
     3. reference to a “party” is to a party to this agreement;
     4. words in the singular include the plural (and vice versa) and words denoting any gender include all genders;
     5. if a word or phrase is defined, any other part of speech or grammatical form of that word or phrase has a corresponding meaning;
     6. reference to any legislation or to any section or provision of it includes any statutory modification or re-enactment of, or any statutory provision substituted for, that legislation, section or provision;
     7. no rules of construction apply to the disadvantage of a party because that party was responsible for the drafting of this agreement or of any of the provisions of this agreement; and
     8. headings are for convenience only and do not affect interpretation or construction.

**SCHEDULE**

|  |  |
| --- | --- |
| **MDTA** | The Material and Data Transfer Agreement between the Recipient and the Health Service dated [*insert MDTA date*] identified as [*insert any contract ID number etc*]. |
| **Health Service** | [*insert Health Service name and details*] |
| **Start Date** | [*insert date later than the MDTA Commencement Date*] |
| **Expiry Date** | [*insert date on or prior to MDTA End Date*] |
| **ATP Authorised Personnel** | [*insert details, and identify any supervisory Authorised Personnel*] |
| **ATP Location** | [*insert details or if appropriate copy the Approved Location from the MDTA*] |
| **ATP Responsible HREC** | [*insert details or if appropriate copy the HREC from the MDTA*] |
| **ATP Project** | [*insert details or if appropriate copy the Project from the MDTA*] |
| **ATP Purpose** | [*insert details or if appropriate copy the Purpose from the MDTA*] |
| **Provision of Material**  (select and delete as appropriate) | (I) The Recipient will provide the Material to the ATP at the ATP Location.  (II) The ATP must (at the ATP's cost) collect the Material from the Recipient's premises identified by the Recipient.  [***Note: Additional terms required if ATP or personnel to enter Health Services premises***] |
| **Material** | [*insert details*] |
| **Material security and additional restrictions** | [*insert details*] |
| **Data** | [*insert details*] |
| **Data format** | [*insert details*] |
| **Data source and custodian approval** | [*insert details*] |
| **Data security** | [*insert details*] |
| **Additional restrictions on use of Data** | [*insert details*] |
| **Special Conditions** | [*insert as appropriate, including to reflect terms in the Schedule to the MDTA (e.g. in relation to Material, retention, additional publication rights etc.*] |

[***Note: If a Fee is payable by the Recipient to the Health Service (or by the ATP to the Recipient to be passed on to the Health Service) that fee should be separately agreed between the Health Service and the Recipient and the Recipient responsible for passing through the terms to the ATP in this agreement***.]

**Executed as an agreement by:**

***[insert appropriate execution blocks]***