

**CONFIDENTIALITY AND DE-IDENTIFIED DATA TRANSFER  
AGREEMENT**

**THIS AGREEMENT** is executed on \_\_\_\_\_ day of \_\_\_\_\_ 20

**BETWEEN**

**THE UNIVERSITY OF MELBOURNE** (ABN 84 002 705 224) of Parkville, Victoria 3010, a body politic and corporate pursuant to the *University of Melbourne Act 2009(Vic)*

(the University)

**AND**

**THE RECEIVING PARTY SPECIFIED IN ITEM 1 OF THE SCHEDULE**

(the Receiving Party)

**RECITALS**

- A.** The University's Twins Research Australia maintains up-to-date baseline information and contact details for twin members willing to participate in research on a network-protected relational database at the University and de-identified data relating to twins.
- B.** The Receiving Party has successfully submitted a TRA Application Form and has received Ethics Approval for the Study.
- C.** The University has agreed to make the De-identified Information available to the Receiving Party for the Study.
- D.** The De-identified Information will be made available on the terms and conditions set out in this Agreement.

**IT IS AGREED AS FOLLOWS**

**1. DEFINITIONS**

1.1 In this Agreement, except where the context otherwise requires:

**"Agreement"** means this agreement together with any schedules or annexures and any amendments made in accordance with this agreement;

**"TRA Application Form"** means the detailed plan of the Study and the request to TRA for access to De-identified Data, as attached to this Agreement at Annexure A;

**"Twins Research Australia"** or **"TRA"** means the not-for-profit volunteer registry set up to facilitate and support medical and scientific studies involving the participation of twins and/or their relatives which is administered and run out of the University;

**"Clean Data Set"** means the final data set of De-identified Information that the Receiving Party will use for analysis, including any new variables and the related algorithm developed by the Receiving Party, in a format compatible with the University's archiving processes;

**"Commencement Date"** means the date on which the agreement is signed by the last party that signs;

## Confidentiality and Data Transfer Agreement – Twins Research Australia

“**Completion Date**” means the completion date described in Item 3 of the Schedule or such other date agreed by the Parties in writing;

“**Confidential Information**” of a Party (**Disclosing Party**) means and includes all:

- (a) unpatented inventions, ideas, know-how, concepts, trade secrets, processes, techniques, software, products;
- (b) other unregistered or unpatented intellectual property;
- (c) financial and business information; and
- (d) all other commercially valuable information of the Disclosing Party, in any form, which is by its nature confidential or which is designated by the Disclosing Party as confidential to it and, in the case of the University, includes the De-Identified Data.

Confidential Information excludes or, as the case requires, ceases to include, information that is or becomes:

- (e) after the date of its disclosure by the Disclosing Party to the other Party (**Recipient**), properly available to the Recipient from a third party having no obligation of confidentiality to the Disclosing Party;
- (f) at the date of its disclosure by the Disclosing Party to the Recipient, already properly in the possession of the Recipient in written form otherwise than by prior confidential disclosure from the Disclosing Party;
- (g) available to the public other than as a result of a breach of confidentiality by the Recipient or its permitted disclosees; or
- (h) demonstrated by the Recipient to be independently developed by an employee or agent of the Recipient having no knowledge of such information the subject of the disclosure.

“**Data Access Policy**” means TRA’s “*Policy for curation of and access to data collected on TRA members*”, as published on the TRA website and updated from time to time;

“**De-identified Data**” means the data held by the University in relation to:

- (a) twin studies; and/or
- (b) twin health and lifestyle information,

that does not identify individuals and is further described at Item 4 of the Schedule and, for the avoidance of doubt, includes the Clean Data Set;

“**Derived Study Outputs**” means any and all discoveries, information, inventions, works, know-how, findings and any other subject matter created or developed by, or in collaboration with, the Receiving Party as a result of the Study Outputs.

“**Ethics Approval**” means the approval by the Responsible HREC of the Study protocol;

“**Fees**” means the fees payable by the Receiving Party under this Agreement set out at Item 7 of the Schedule;

“**Intellectual Property Rights**” means all intellectual property rights subsisting anywhere in the world, including but not limited to, the following rights:

- (a) patents, copyright, rights in circuit layouts, designs, trade and service marks (including goodwill in those marks), domain names and trade names and any right to have confidential information kept confidential; and

## Confidentiality and Data Transfer Agreement – Twins Research Australia

- (b) any application or right to apply for registration of any of the rights referred to in paragraph (a),

whether or not such rights are registered or capable of being registered.

**“Parties”** means the parties to this Agreement and their respective successors and permitted assigns, and Party means any one of them;

**“Special Conditions”** means the conditions set out at Item 8 of the Schedule;

**“Study”** means the study utilising the De-identified Data and described in Item 5 of the Schedule;

**Study Outputs”** means any and all discoveries, information, inventions, works, know-how, findings and any other subject matter created or developed in the course of undertaking the Study;

**“Researcher”** means the member of the Receiving Party who has requested the De-identified Data and named at Item 2 of the Schedule;

**“Receiving Party”** means the Party identified as the Receiving Party at Item 1 of the Schedule and includes its respective successors and permitted assigns;

**“Responsible HREC”** means the human research and ethics committee described in Item of 6 the Schedule; and

**“Term”** means the term of this Agreement as described in clause 2.

## 2. TERM

This Agreement commences on the Commencement Date and remains in force until the Completion Date unless otherwise terminated by the University in accordance with clause 9.

## 3. PAYMENT OF FEES

- 3.1 Subject to payment of the Fees and compliance with this Agreement, the University agrees to disclose the De-identified Data to the Receiving Party on the terms of this Agreement.
- 3.2 The Receiving Party must pay the Fees within 30 days of receipt of the relevant invoice.

## 4. USE OF THE DE-IDENTIFIED DATA, STUDY OUTPUTS AND DERIVED STUDY OUTPUTS

- 4.1 Subject always to clause 4.2, the Receiving Party agrees to act in accordance with this Agreement, including the Special Conditions, and the Data Access Policy when using the De-identified Data.
- 4.2 If there is any inconsistency between:
- (a) the Special Conditions;
  - (b) the terms and conditions in the body of this Agreement; and
  - (c) the Data Access Policy;
- the documents will prevail in the order listed above to the extent of any inconsistency.
- 4.3 The De-identified Data may only be used:
- (a) for the Study; and

## **Confidentiality and Data Transfer Agreement – Twins Research Australia**

- (b) in accordance with this Agreement.
- 4.4 The De-identified Data will not be provided to the Receiving Party until the University has received a copy of the relevant ethics application approved by the Responsible HREC and the final Ethics Approval (including the project number) from the Receiving Party.
- 4.5 The De-identified Data must be used in a manner that is consistent with the Ethics Approval submitted to the University pursuant to clause 4.4.
- 4.6 The Receiving Party must not, under any circumstances:
  - (a) re-use the De-identified Data for any activity outside the scope of the Study, even if the activity is an extension of the Study, without prior written consent from the University; or
  - (b) breach the warranties set out at clause 8.1; or
  - (c) identify or attempt to identify the individuals whose information appears in the De-identified Data or attempt to contact such individuals.
- 4.7 The Receiving Party must:
  - (a) upon the earlier of the Completion Date or termination of this Agreement, deliver to the University a copy of the Study Outputs, including a copy of the Clean Data Set;
  - (b) provide the University with regular reports on the progress of the Study;
  - (c) provide the University with a final report notifying it of the Study Outputs;
  - (d) notify the University of any proposed use of the Study Outputs or Derived Study Outputs for any future projects in relation to which the Receiving Party intends to be a participant or collaborator; and
  - (e) notify the University of any Derived Study Outputs as soon as practicable.
- 4.8 Nothing in this Agreement prevents the University from using or disclosing the De-identified Data to any third party and authorising such third party to use or disclose the De-identified Data, whether for commercial or non-commercial purposes and whether the third party is a commercial or not-for-profit organisation.

### **5. INTELLECTUAL PROPERTY RIGHTS**

- 5.1 Copyright in the Clean Data Set vests upon its creation in the University and the Receiving Party hereby assigns to the University all of its right, title or interest in the copyright in the Clean Data Set (including future copyright) and the Receiving Party must do all things and execute all documents necessary to give effect to this clause and render all assistance reasonably required by the University for the purpose of confirming, recording or perfecting the assignment under this clause 5.1.
- 5.2 To the extent that the University owns copyright in the De-identified Data and subject to clause 6, the University grants the Receiving Party a non-exclusive, royalty-free licence to reproduce, modify and adapt the De-identified Data for the purpose of conducting the Study only for the Term.

### **6. CONFIDENTIALITY OBLIGATIONS**

- 6.1 In respect of the De-identified Data specifically, the Receiving Party must:

## Confidentiality and Data Transfer Agreement – Twins Research Australia

- (a) not disclose the De-identified Data nor permit third parties who are not named in the original approved TRA Application Form attached as Annexure 1 to this Agreement to use the De-identified Data;
- (b) within the Receiving Party, restrict access to the De-identified Data to the minimum number of individuals necessary to complete the Study;
- (c) establish and maintain the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the De-identified Data and to prevent unauthorised use or access to the De-identified Data;
- (d) subject any Study Outputs, findings or manuscripts proposed for public release (including, without limitation, abstracts, presentations, publications, collaborative research activities) to a stringent review to assure that De-identified Data confidentiality is maintained.

6.2 In respect of all Confidential Information generally, the Recipient must:

- (a) keep all Confidential Information confidential;
- (b) not use Confidential Information in any way which would be harmful to the best interests of the Disclosing Party;
- (c) immediately notify the University in the event of any disclosure which is strictly required by law;
- (d) not use any Confidential Information in any way other than as otherwise contemplated by this Agreement without the prior written permission of the Disclosing Party; and
- (e) ensure that all employees or agents to whom Confidential Information is disclosed are legally bound to keep the Confidential Information confidential and not to use the Confidential Information except as permitted under this Agreement.

## 7. PUBLICATIONS

- 7.1 The Receiving Party must include a statement approved prior to publication by the University to acknowledge the use of the University's TRA and that the source of data was the University's TRA.
- 7.2 Where the Receiving Party intends to publish in relation to the Study, it must provide a copy of the proposed publication to the University, in confidence, prior to releasing the publication.
- 7.3 Where the Receiving Party provides a copy of a proposed publication to the University, the University must reply in writing within one (1) month stating whether it approves or does not approve the publication. The University must not withhold such approval unless it reasonably believes that the publication:
  - (a) would harm, prejudice or in any other way injure TRA or University; or
  - (b) contains the University's Confidential Information.
- 7.4 If the University does not give the Receiving Party a reply within one (1) month of receiving the request to publish, then the consent to publish shall be deemed to have been given.
- 7.5 The University will not have editorial rights over the content of publications by the Receiving Party.

## **Confidentiality and Data Transfer Agreement – Twins Research Australia**

- 7.6 The Receiving Party will ensure that all publications arising from the Study list all relevant contributors as authors in accordance with generally accepted conventions relating to authorship of peer reviewed publications.

### **8. WARRANTIES AND RISK**

- 8.1 The Receiving Party warrants that:
- (a) it will not use the Study Outputs or De-identified Data for market research or for purposes other than for health, social or medical research; and
  - (b) after the Completion Date or termination of this Agreement, it will not use the De-identified Data for any purpose unless otherwise approved by the University.
- 8.2 The Receiving Party acknowledges and agrees that, to the extent permitted by law, the University excludes all warranties, express or implied, in relation to the De-identified Data, including without limitation warranties of fitness for a particular use or accuracy.
- 8.3 The Receiving Party accepts sole responsibility and liability for its use of the De-identified Data and Derived Study Outputs, will use the De-identified Data at its own risk, and must obtain and maintain adequate insurance in respect of its use of the De-identified Data;
- 8.4 The Receiving Party indemnifies the University and its officers, staff, students, contractors, representatives and agents against all loss, liability, damage, (whether to persons or property), costs and expenses (including without limitation legal expenses), claims, demands, suits or other actions arising out of the Receiving Party's handling, use and disposal of the De-identified Data.

### **9. FUNDING SOURCES**

The Receiving Party undertakes to advise the University of any and all sources of funding for the Study.

### **10. TERMINATION & DESTRUCTION OF DATA**

- 10.1 The Receiving Party agrees that in the event that the University determines or has a reasonable belief that the Receiving Party has breached the terms of this Agreement, the University may terminate this Agreement immediately upon provision of written notice to the Receiving Party.
- 10.2 The University may terminate this Agreement upon provision of 30 days' written notice to the Receiving Party if the University determines in its sole discretion that the reputation, integrity or standing of TRA or the University may be adversely impacted by continued association with the Study.
- 10.3 Upon receipt of written notice pursuant to clause 10.1 or 10.2, the Receiving Party will immediately return the De-Identified Data and Clean Data Set to the University and delete all records (whether tangible or electronic) of the De-Identified Data and Clean Data Set and certify to the University in writing that this obligation has been complied with.
- 10.4 All rights and obligations of the parties under this Agreement capable of surviving termination or expiration of this Agreement will do so including, without limitation, the provisions of clause 3, 4, 5, 6, 7, 8 and 10.

### **11. GOODS AND SERVICES TAX**

- 11.1 For the purposes of this clause 11, the value of supplies made by each Party under this Agreement is as follows:

## Confidentiality and Data Transfer Agreement – Twins Research Australia

- (a) unless expressly stated to the contrary, the consideration to be provided for any taxable supply made by one party to the other under this Agreement has been calculated without regard to, and is exclusive of, GST;
- (b) the consideration referred to in paragraph (a) shall be increased by the amount of any GST;
- (c) the Party receiving any payment for a taxable supply under this Agreement shall provide to the Party making a payment for a taxable supply a tax invoice in respect of that payment; and
- (d) the Party receiving any payment under this Agreement for a taxable supply shall do all things necessary (including, without limitation, registering with any required Government authority) to enable the party making a payment for a taxable supply to claim any credits or other benefits under the relevant law relating to GST.

### 12. DISPUTE

- 12.1 A Party claiming that a dispute has arisen under this Agreement (“**Dispute**”) must notify the other Party giving written details of the Dispute. The Parties agree to negotiate in good faith on a commercially realistic basis to resolve the Dispute and will refer resolution of the Dispute to officers within each Party who are authorised to hear the Dispute before commencing any legal proceedings in relation to the Dispute.
- 12.2 Any Dispute which cannot be settled between the Parties within a reasonable time must be referred for determination by a person appointed for that purpose by the Parties and failing Agreement, appointed by the President of the Institute of Arbitrators and Mediators Australia (Victorian Division). Any determination made under the above clause is binding on the Parties and the *Commercial Arbitration Act 1984 (Vic)* applies to the determination except to the extent otherwise agreed by the Parties. Nothing in this clause 12 will prevent a Party from seeking interlocutory relief.

### 13. GENERAL

- 13.1 **Proprietary Rights.** The Receiving Party obtains no proprietary rights of any kind to any Confidential Information as a result of a disclosure to it under this Agreement.
- 13.2 **Method of Disclosure.** The obligations in this Agreement apply irrespective of the method of disclosure whether in writing, in computer software, orally, by demonstration, description, inspection or otherwise.
- 13.3 **Relief.** The Receiving Party acknowledges and agrees that monetary damages would be an insufficient remedy for breach of this Agreement and that, in addition to any other remedy available, the University is entitled to injunctive relief to prevent a breach of this Agreement and to compel specific performance of this Agreement.
- 13.4 **Waiver.** A Party's failure to exercise or delay in exercising a right or power does not operate as a waiver of that right or power and does not preclude the future exercise of that right or power.
- 13.5 **Severance.** Any illegal or invalid provision of this Agreement will be severable and all other provisions will remain in full force and effect.
- 13.6 **Relationship of the Parties.** The Parties are independent contracting parties, and nothing in this Agreement shall make either Party the agent, partner or legal representative of the other

## Confidentiality and Data Transfer Agreement – Twins Research Australia

Party for any purpose whatsoever, nor does it grant either Party any authority to assume or to create any obligation on behalf of or in the name of the other Party.

- 13.7 **Assignment.** A Party will not assign or transfer all or any of its rights or obligations under this Agreement without the prior written consent of the other Party.
- 13.8 **Amendment.** This Agreement may only be amended in writing signed by the Parties.
- 13.9 **Burden of Proof.** The burden of showing that any Confidential Information is not subject to the obligations of confidentiality in this Agreement will rest on the Receiving Party.
- 13.10 **Governing Law.** This Agreement is governed by the laws of the State of Victoria, Australia. The Parties submit to the exclusive jurisdiction of the courts of the State of Victoria and any courts which may hear appeals from those courts.
- 13.11 **Entire agreement.** This Agreement contains the whole of the agreement between the Parties regarding their mutual obligations of confidentiality.

**EXECUTED** as an Agreement as follows:

**SIGNED** for and on behalf of **THE** )  
**UNIVERSITY OF MELBOURNE** )  
in the presence of: )

.....  
Signature of authorised person

.....  
Signature of Witness

.....  
Office held

.....  
Name of Witness  
(block letters)

.....  
Name of authorised person  
(block letters)

**SIGNED** for and on behalf of **RECEIVING** )  
**PARTY** )  
in the presence of: )

.....  
Signature of authorised person

.....  
Signature of Witness

.....  
Office held

.....  
Name of Witness  
(block letters)

.....  
Name of authorised person  
(block letters)

[The **last party** to sign this Agreement must complete the date field on the first page]





## Confidentiality and Data Transfer Agreement – Twins Research Australia

**ITEM 5** *[Please provide a brief description of the Study, including all sources of funding for the Study e.g. NHMRC grant ID# and title]*  
**Study**

**ITEM 6** *[Please insert description of the responsible human research and ethics committee, which must be an NHMRC-recognised committee]*  
**Responsible  
HREC**

**ITEM 7** *[Please complete]*

**Fee**

**ITEM 8** *[Please complete]*

**Special  
Conditions**

## **Annexure A**

*Please attach the completed TRA Application Form*