

AUSTRALIAN TWIN REGISTRY SERVICES AND ACCESS 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)* through the Australian Twin Registry.

(the University)

AND

THE RECIPIENT SPECIFIED IN ITEM 1 OF THE SCHEDULE

(the Receiving Party)

RECITALS

- A. The Australian Twin Registry (“**ATR**”) 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 (“**Twin Members**”).
- B. The Receiving Party has successfully submitted an ATR Application Form and has received Ethics Approval for the Study.
- C. The University has agreed to make the Identifying Information available to the Receiving Party for the Study.
- D. The Identifying 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;

“**ATR Application Form**” means the detailed plan of the Study and the request to the ATR for access to potential Identifying Information, as attached to this Agreement at Annexure A;

“**ATR ID**” means the unique identification number provided to the Receiving Party by the University upon provision of the Identifying Information;

“**Australian Twin Registry**” or “**ATR**” 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 that the Receiving Party will use for analysis in a format compatible with the University’s archiving processes, which includes the ATR ID but does not include Identifying Information;

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

“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” means the Identifying Information, intellectual property, financial and business information and all other commercially valuable information of the University which the University regards as confidential to it and all copies, notes and records and all related information generated by the Receiving Party based on or arising out of any such disclosure. Confidential Information excludes, or as the case requires, ceases to include information which is, or becomes:

- (a) available to the public at the date of its disclosure to the Receiving Party;
- (b) at the date of its disclosure to the Receiving Party, already properly in the possession of the Receiving Party in written form otherwise than by prior confidential disclosure from the University;
- (c) after the date of its disclosure to the Receiving Party, available to the public from sources other than the Receiving Party;
- (d) after the date of its disclosure to the Receiving Party, properly available to the Receiving Party from a third party having no obligation of confidentiality to the University;
- (e) demonstrated by the Receiving Party to be independently developed by an employee or agent of the Receiving Party having no knowledge of such information the subject of the disclosure; or
- (f) required to be disclosed by law;

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

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

“Estimate Fee” means an indicative estimate of the total amount of Fees payable by the Receiving Party as set out in Item 7 of the Schedule;

“Fees” means the fees payable by the Receiving Party under this Agreement;

“Guidelines” means the *“Working with ATR”* guidelines prepared by the University, as may be updated from time to time and posted on the ATR website;

“Identifying Information” means any information that enables a Participant to be identified in relation to:

- (a) particular components of Study Data;
- (b) particular components of a Clean Data Set;
- (c) Personal or Health Information; or
- (d) their ATR ID;

“Participants” means the Twin Members who, through the process approved by the University’s Human Research Ethics Committee, have given permission to the ATR to disclose certain Personal or Health Information to the Receiving Party;;

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

“Personal or Health Information” means personal information as defined in the *Information Privacy Act 2000 (Victoria)* or health information as defined in the *Health Records Acts 2001 (Victoria)*;

“PLS” means the plain language statement for the Study;

“Privacy Acts” means the *Information Privacy Act 2000 (Victoria)* and the *Health Records Act 2001 (Victoria)*;

“Researcher” means the member of the Receiving Party who has requested the Identifying Information and named at Item 2 of the Schedule;

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"**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;

"**Study**" means the study described in Item 5 of the Schedule;

"**Study Data**" means study data and results from samples generated from tests and measures conducted within the Study, which may include the ATR ID but does not include Identifying Information;

"**Study Subject**" means a person recruited to participate in the Study (who may be a Participant);

"**Term**" means the term of this Agreement as described in clause 2; and

"**University Purposes**" means:

- (a) to use Study Data and ATR ID confidentially to enhance the ATR's information about individual Participants but not to make such information available to third parties without the prior consent of Participants; and
- (b) to make de-identified Study Data available to third party Researchers in accordance with the Data Access Policy and the terms of a data access agreement between the University and the third party researcher.

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 12.

3 PAYMENT OF FEES

3.1 Subject to payment of the Fee and compliance with this Agreement, ATR agrees to solicit Twin Members to participate in the Study until:

- (a) the Term expires; or
- (b) the Receiving Party directs the ATR to cease solicitation activities,

whichever occurs sooner.

3.2 The Receiving Party understands and acknowledges that for the reasons set out at clause 10.3, the Estimate Fee is only an indicative estimate and that Fees will be invoiced by the University in accordance with clause 3.3 below.

3.3 The Receiving Party acknowledges that the University's billing cycle occurs twice a year on the 30th June and 31st December of every calendar year ("**Billing Date**"). The University will provide an invoice to the Receiving Party for Fees payable for the provision of Identifying Information in the 6 month period ending on the most recent Billing Date within 30 days of that Billing Date, unless the Receiving Party and the University have agreed that the Fee will be paid on an upfront basis.

3.4 The Receiving Party must pay the relevant Fees within 30 days of receipt of the invoice for the relevant Fees.

4 USE OF THE IDENTIFYING INFORMATION, STUDY DATA AND RESULTS

4.1 Subject always to clause 4.2, the Receiving Party agrees to act in accordance with the Guidelines and Data Access Policy when using the Identifying Information.

4.2 If there is any inconsistency between:

- (a) the terms and conditions in the body of this Agreement;
- (b) the Guidelines; and
- (c) the Data Access Policy;

the documents will prevail in the order listed from (a) to (c) above to the extent of any inconsistency.

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- 4.3 The Identifying Information may only be used to contact the Participants:
- (a) for the Study; and
 - (b) in accordance with this Agreement; and
 - (c) in accordance with the Guidelines.
- 4.4 The Identifying Information 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 Identifying Information 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 at all times:
- (a) store the Identifying Information separately from the Study Data and Clean Data Set; and
 - (b) ensure that the ATR ID is attached to each component of the Study Data and Clean Data Set.
- 4.7 The Receiving Party must not, under any circumstances:
- (a) re-use the Identifying Information to contact the Participants for any activity outside the scope of the Study, even if the activity is an extension of the Study; or
 - (b) use the Study Data or results for market research or for purposes other than health, social and medical research; or
 - (c) use the Identifying Information for any other purposes except as permitted under this Agreement.
- 4.8 Subject to this clause, the Receiving Party is free to conduct sub-studies using the Study Data if those sub-studies do not use the Identifying Information. In the event that the Receiving Party conducts such sub-studies, the Receiving Party must:
- (a) promptly inform the University of any such sub-studies utilising the Study Data (as an extension of the original ATR Application or any secondary analysis of the Study Data that may be required); and
 - (b) provide the University with all reasonable information in relation to a matter notified pursuant to clause 4.8(a) at the University's request.

5 PRIVACY AND PERSONAL INFORMATION

- 5.1 Regardless of any other provisions contained in this Agreement, the Receiving Party must not disclose any Personal or Health information other than to the University in accordance with clauses 7.2 and 8 of this Agreement.
- 5.2 The Receiving Party agrees to comply with the Privacy Acts, any approved privacy codes and with the University's privacy policy and guidelines as amended from time to time in respect of any Personal or Health Information held by the University which the Receiving Party becomes aware of or has access to in connection with this Agreement and any Personal or Health Information collected, held, managed, used, disclosed or transferred by the Receiving Party in connection with this Agreement. The University's privacy policy can be located at:
- <http://www.unimelb.edu.au/unisec/privacy>
- 5.3 The Receiving Party must report immediately to the University any use or disclosure of the Identifying Information or any Personal or Health Information other than as permitted by this Agreement, and will take all reasonable steps to mitigate the effects of such improper use or disclosure, cooperating with all reasonable requests by the University towards that end.

6. CONFIDENTIALITY OBLIGATIONS

- 6.1 In respect of the Identifying Information specifically, the Receiving Party must:

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- (a) not disclose the Identifying Information nor permit third parties who are not named in the original approved ATR Application Form attached as Annexure 1 to this Agreement to use the Identifying Information;
- (b) within the Receiving Party, restrict access to the Identifying Information 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 Identifying Information and to prevent unauthorised use or access to the Identifying Information;
- (d) not release any Study Data or other findings or information derived from the Identifying Information if this contains any combination of data elements that might allow for identification or the deduction of a Participant's identity, other than to the University in accordance with clauses 7.2 and 8 of this Agreement; and
- (e) subject any Study Data, findings or manuscripts proposed for public release (e.g., abstracts, presentations, publications) to a stringent review to assure that Identifying Information confidentiality is maintained and that individual study Participants cannot be identified.

6.2 In respect of all Confidential Information generally, the Receiving Party 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 University;
- (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 for the Study or as otherwise contemplated by this Agreement without the prior written permission of the University; 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 for the Study.

7. DOCUMENTATION AND AUDITING

7.1 The Receiving Party agrees to provide to the University:

- (a) a copy of the PLS before the Receiving Party first starts recruiting subjects (including any Participants) for the Study; and
- (b) a copy of any proposed revised PLS at the time the proposed revised PLS is submitted for approval by the Responsible HREC; and
- (c) a copy of the form of any consent form to be signed by any Study Subject upon such form being approved by the Responsible HREC, including any revised consent forms approved by the Responsible HREC.

7.2 The Receiving Party agrees that the University is entitled to, at reasonable times and subject to the provision of reasonable prior notice by the University, access and make copies of each consent form signed by a Study Subject, for purposes associated with this Agreement or any review of the Receiving Party's compliance with this Agreement.

8 UPDATING THE REGISTRY AND DATA ARCHIVING

8.1 The Receiving Party acknowledges that the ATR database is maintained as a valuable resource to the research community. The Receiving Party therefore agrees to ask Participants to consent to:

- (a) all zygosity results collected for the Study to be provided to the ATR by the Receiving Party;
- (b) any updates to contact details or information of the Participants gathered during the period of the Study be provided to the ATR by the Receiving Party.

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- 8.2 Subject to Participant consent being obtained by the Receiving Party pursuant to clause 8.1, the Receiving Party agrees to provide to the University within 30 days of the information becoming available:
- (a) all zygosity results collected for the Study with the relevant ATR ID, to be added to the ATR database; and
 - (b) any updates to contact details or information of the Participants gathered during the period of the Study with the relevant ATR ID.
- 8.3 If the Receiving Party identifies any twin pairs as part of their Study who are not existing Twin Members of the ATR, the Receiving Party agrees to inform the twin pairs about the ATR facility and provide them with ATR's contact details within 30 days of becoming aware of this information. Registration forms to register with the ATR are available from the ATR coordinator.
- 8.4 The Receiving Party agrees to:
- (a) provide each Study Subject with a plain language statement and use reasonable endeavours to obtain informed consents from each Study Subject relating to use of the Clean Data Set, ATR ID and Identifying Information for University Purposes in the form:
 - (i) provided by the University; or
 - (ii) approved by the University; and
 - (b) provide the University with the originals of the consents referred to in clause 8.4(a) or, where the consents are obtained online, appropriate evidence of such consents; and
 - (c) in relation to data contained within the Clean Data Set for which consents have been obtained pursuant to clause 8.4(a), provide the University with a copy of such data (including relevant ATR ID) on the completion of the cleaning of the Study Data (or by such other date as agreed by the University in writing) for the University Purposes.
- 8.5 The Parties agree to negotiate in good faith in relation to the collection of consents and bio samples by the Receiving Party in relation to the Participants on behalf of the University, including the ownership, storage, use and derivative results of such bio samples. The parties agree to enter further agreements in relation to the outcomes of those negotiations.

9 PUBLICATIONS

- 9.1 The Receiving Party must include a statement in a form approved by the University in all publications arising from the Study to acknowledge the use of the ATR through the University.
- 9.2 The Receiving Party must advise the University of all publications arising from the Study and will provide the University with an electronic copy of any such publications within 30 days of publication.
- 9.3 The Receiving Party must advise the University of all subsequent publications arising from any sub-studies utilising the Study Data as an extension of the original ATR Application or any secondary analysis of the Study Data and will provide the University with an electronic copy of any such publications within 30 days of publication.

10 WARRANTIES

- 10.1 The Receiving Party warrants that:
- (a) under no circumstances will it coerce or pressure the Participants to participate in the Study or to continue their participation in the Study;
 - (b) it will only communicate with the Participants in relation to the Study. Any other additional or peripheral information or communication with the Participants for any purpose not related to the Study must first be approved by the University in writing prior to such contact;

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- (c) it will not use the Study Data or results for market research or for purposes other than for health, social or medical research; and
- (d) after the Completion Date or termination of this Agreement, it will not contact any of the Participants or use the Identifying Information for any purpose unless otherwise approved by the University.

10.2 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 Identifying Information, including without limitation warranties of fitness for a particular use or accuracy.

10.3 The Receiving Party acknowledges and agrees that Twin Members have absolute discretion to elect or decline to become Participants and as such, ATR makes no warranties, representations or guarantees that it can provide the Receiving Party with a particular number of Participants or do so within a particular timeframe. The Receiving Party acknowledges and agrees that the Fee will be payable whether or not the desired number of Participants have been recruited by ATR in the desired timeframe.

11 FUNDING SOURCES

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

12 TERMINATION & DESTRUCTION OF DATA

12.1 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.

12.2 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 the ATR or the University may be adversely impacted by ATR's continued association with the Study.

12.3 Upon the earlier of the Completion Date or termination of this Agreement, the Receiving Party must:

- (a) destroy the Identifying Information and all copies of the Identifying Information unless an exemption is granted in writing by the University. The Receiving Party must provide a certification from an authorised officer of the Receiving Party confirming that the Identifying Information has been appropriately destroyed in compliance with this Agreement unless an exemption has been granted in writing by the University under this clause; and
- (b) comply with the obligations set out at clause 8.

12.4 The Receiving Party must also retain the ATR ID after termination of this Agreement if required by the University.

12.5 If the Researcher leaves the employ of the Receiving Party, the Receiving Party will notify the University in writing at least 14 days before the Researcher leaves. The Researcher is not permitted to take the Identifying Information with them without the prior written permission of the University. Within 14 days of the Researcher leaving, the Receiving Party agrees to destroy the Identifying Information and all derivative data sets. The Receiving Party will, if required by the University, provide a certification from an authorised officer of the Receiving Party confirming that the Identifying Information has been appropriately destroyed in compliance with this Agreement.

12.6 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 4, 5, 6, 8, 9 and 12.

13 GOODS AND SERVICES TAX

For the purposes of this clause 13, the value of supplies made by each Party under this Agreement is as follows:

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- (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.

14 DISPUTE

- 14.1 If the Receiving Party at any time disagrees with or has a dispute with the ATR regarding the approval, processing or coordination of the Study, a dispute resolution process is available and documented at:
http://www.twins.org.au/files/atr_dispute_resolution_process_final.pdf
- 14.2 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.
- 14.3 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 14.3 will prevent a Party from seeking interlocutory relief.

15 GENERAL

- 15.1 **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.
- 15.2 **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.
- 15.3 **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.
- 15.4 **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.
- 15.5 **Severance.** Any illegal or invalid provision of this Agreement will be severable and all other provisions will remain in full force and effect.
- 15.6 **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 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.
- 15.7 **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.
- 15.8 **Amendment.** This Agreement may only be amended in writing signed by the Parties.

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- 15.9 **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.
- 15.10 **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.
- 15.11 **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]

SCHEDULE

ITEM 1: THE PARTIES

**The
University**

Legal Name: The University of Melbourne

Address: Attention: Executive Director, Research
The University of Melbourne
VIC 3010

Fax No: +61 3 9347 9326

ABN: 84 002 705 224

**Receiving
Party**

Legal Name: *[Please complete]*

Address:

Phone:

Fax No:

ABN:

ITEM 2:

**Researcher
Information**

Name: *[Please complete]*

Institution/ Organisation:

Address:

Telephone:

Fax No:

Email:

ITEM 3

**Completion
Date**

[Please complete relevant date]

ITEM 4

Details of Identifying Information [Please complete]

ITEM 5

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

ITEM 6

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

ITEM 7

Estimate Fee (indicative estimate) [Please complete]

Annexure A

Please attach the completed ATR Application Form