TWINS RESEARCH AUSTRALIA
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)

(the University)

AND

THE RECIPIENT 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 ("**Twin Members**").

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 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;

"BioBank Sample" means a supplementary sample of biological material collected from a Study Subject in the course of carrying out the Study for University BioBank Purposes in accordance with the TRA BioBank Policy;

"Clean Data Set" means the:

(a) final data set; or
(b) in the case of a longitudinal study, the final data set for each stage of such longitudinal study,

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, which includes the TRA ID but does not include Identifying Information;

"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" of a Party (**Disclosing Party**) means and includes all unpatented inventions, ideas, know-how, concepts, trade secrets, processes, techniques, software, products and all other unregistered or unpatented intellectual property, financial and business information and 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 Identifying Information. Confidential Information excludes or, as the case requires, ceases to include, information that is or becomes:

(a) 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;

(b) 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;

(c) available to the public other than as a result of a breach of confidentiality by the Recipient or its permitted discloses; or

(d) 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;

"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 TRA*" guidelines prepared by the University, as may be updated from time to time and posted on the TRA 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 TRA ID;

"Participants" means the Twin Members who, through the process approved by the University's Human Research Ethics Committee, have given permission to TRA 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 *Privacy and Data Protection Act 2014 (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 *Privacy and Data Protection Act 2014 (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;

"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 TRA 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;

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

"TRA Biobank Policy" means TRA's "*Policy for collection and use of bio specimens from members of TRA"*, as published on the TRA website and updated from time to time;

"TRA ID" means the unique identification number provided to the Receiving Party by the University upon provision of the Identifying Information;

"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;

and

"University Purposes" means:

(a) to use Study Data and TRA ID confidentially to enhance the TRA'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.

"University BioBank Purposes" means long-term storage and future use for ethically approved research purposes.

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, TRA agrees to solicit Twin Members to participate in the Study until:

(a) the Term expires; or

(b) the Receiving Party directs TRA 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.

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 TRA 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 TRA 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:

(a) not disclose the Identifying Information 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 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 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 for the Study or 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. 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, DATA ARCHIVING AND BIOBANKING

8.1 The Receiving Party acknowledges that the TRA database is maintained as a valuable resource to the research community. In accordance with clause 8.4 (a), the Receiving Party therefore agrees to ask Participants to consent to:

(a) all zygosity results collected for the Study to be provided to TRA 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 TRA by the Receiving Party;

(c) all information contained on the Clean Dataset to be provided to TRA by the Receiving Party.

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 TRA ID, to be added to the TRA database;

(b) any updates to contact details or information of the Participants gathered during the period of the Study with the relevant TRA ID; and

(c) all information contained on the Clean Dataset to be provided to TRA by the Receiving Party.

8.3 If the Receiving Party identifies any twin pairs as part of their Study who are not existing Twin Members of TRA, the Receiving Party agrees to inform the twin pairs about the TRA facility and provide them with TRA's contact details within 30 days of becoming aware of this information. Registration forms to register with TRA are available from the TRA coordinator.

8.4 The Receiving Party agrees to:

(a) provide each Study Subject with a PLS and use reasonable endeavours to obtain informed consents from each Study Subject relating to use of the Clean Data Set, TRA ID and Identifying Information for University Purposes and use of the Biobank Samples for University BioBank 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 TRA ID) and grants the University a perpetual, irrevocable, non-exclusive, worldwide, royalty free, paid-up licence to use, adapt, reproduce, communicate and modify the Clean Data Set, including the right to grant sub- licences, for the University Purposes.

8.5 Where the Study involves the collection of biological samples, and the Study Subject signs an appropriate consent in accordance with clause 8.4(a), the Receiving Party agrees to:

(a) collect a BioBank Sample from each consenting Study Subject;

(b) store or dispatch the BioBank Sample in accordance with the Schedule;

(c) provide the University with

information regarding:

(i) type and quantity;

(ii) collection method;

(iii) processing;

(iv) storage method;

(v) storage location; and

(vi) TRA ID.

(c) 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

(d) if the Receiving Party retains custody of the BioBank Samples, not use the Bio Bank Samples for any purpose other than as directed by the University for University BioBank Purposes.

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 TRA 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.

9.10 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 TRA 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;

(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, TRA 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 TRA 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 TRA or the University may be adversely impacted by TRA'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 TRA 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:

(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 TRA 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.

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*]
ITEM 8 **Storage/Despatch of BioBank samples**	

Annexure A

Please attach the completed TRA Application Form