

Ten to Men: The Australian Longitudinal Study on Male Health

Terms and Conditions of Data Access and Use (June 2019)

1. DEFINED TERMS AND INTERPRETATION

1.1. Defined terms

1.1.1. The following definitions apply unless the context requires otherwise:

Agreement means the Data User Agreement between the Data User and AIFS together with any schedules or annexures and any amendments made in accordance with the Agreement.

Australian Privacy Principle has the same meaning as it has in the *Privacy Act 1988* (Cth).

Business Day means a day that is not a Saturday, Sunday or a public holiday.

Commencement Date means the date specified in Item 8 of Schedule 1.

Confidential Information means information provided by AIFS that:

- a. is by its nature confidential;
 - b. is designated in writing by AIFS as confidential;
 - c. is personal information under the Privacy Act; or
 - d. the User knows or ought to know is confidential,
- and includes:
- e. the Datasets, if in a form which discloses any of the information referred to in paragraphs (a)-(d) above;
 - f. other information comprised in or relating to any Intellectual Property of AIFS or third parties (where that information is provided by a third party on behalf of AIFS) if in a form which discloses any of the information referred to in paragraphs (a) – (d) above; or
 - g. information relating to the internal management and structure of AIFS,
- but does not include information which:
- h. is or becomes public knowledge other than by breach of the Deed of the Agreement, or other contractual or legislative confidentiality obligations; or
 - i. the User can establish by written evidence has been independently developed or acquired by the User without breach of any obligation of confidence.

Data means the data and related information pertaining to the Study which has been deposited by AIFS at the Australian Data Archive.

Dataset means a specific group of Data and related information pertaining to the Study.

Derivatives means Intellectual Property:

- a. subsisting in any improvements, or modifications to the Data (**Data Derivatives**); and
- b. arising from the User's use of the Data that the User develops (**Other Derivatives**).

Eligible Data Breach has the same meaning as it has in the Privacy Act.

End Date means the date specified in Item 9 of Schedule 1, or otherwise as agreed

between the Parties in writing.

Intellectual Property means all rights resulting from intellectual activity whether capable of protection by statute, common law or in equity and including copyright, discoveries, inventions, patent rights, registered and unregistered trademarks, design rights, circuit layouts and plant varieties and all rights and interests of a like nature including but not limited to methods and techniques, together with any documentation relating to such rights and interests whether registered or unregistered and existing in Australia or elsewhere in the world and whether created before or after the Commencement Date.

NHMRC Guidelines mean the *Australian Code for the Responsible Conduct of Research* published by the National Health and Medical Research Council (NHMRC) as updated from time to time.

Notice means any notice, demand, consent or other communication whatsoever given or made in writing under the Agreement to the relevant Contact Officer specified in Item 1 of Schedule 1.

Parties means the parties to the Agreement and their respective successors and permitted assignees, and '**Party**' means any one of them.

Personal Information has the same meaning as it has in the Privacy Act.

Privacy Act means the *Privacy Act 1988* (Cth).

Project means the project described in Item 2 of Schedule 1.

Special Conditions means any special conditions listed in Item 3 of Schedule 1 of the Agreement.

Specified Personnel means the User personnel specified in Item 5 of Schedule 1 of the Agreement.

Study means the research study entitled the Australian Longitudinal Study on Male Health or 'Ten to Men' being undertaken by AIFS under an agreement between AIFS and the Commonwealth.

Term means the period from the Commencement Date to the End Date of the Agreement.

User means the person or organisation named in the Data User Agreement.

1.2. Interpretation

1.2.1. In the Agreement, unless the context requires otherwise:

- a. a reference to the Agreement or any other instrument includes any variation or replacement of any of them;
- b. the singular includes the plural and vice versa;
- c. the word 'person' includes a firm, partnership, body corporate, unincorporated association or authority;
- d. reference to a 'person' includes the executors, administrators, successors, substitutes (including persons taking by novation) and assigns of the person;
- e. time is calculated exclusive of the Commencement Date of the Agreement;

- f. if an event is to occur on or by a given day which is not a Business Day, the given day is taken to be the next Business Day;
- g. headings are for convenience and do not affect interpretation;
- h. unless specified to the contrary, reference to “dollars” or “\$” is to an amount in Australian currency;
- i. a covenant, representation or warranty in favour of two or more persons is for the benefit of them jointly and severally;
- j. a covenant representation or warranty on the part of two or more persons binds them jointly and severally;
- k. reference to any statute, or any particular provision or provisions of a statute, includes any amendment, replacement or re-enactment for the time being in force and any by-laws, statutory instruments, rules, regulations, notices, orders, directions, consents or permissions made there under and any conditions attaching thereto; and
- l. reference to a clause, schedule or annexure is a reference to a clause of, or a schedule or annexure to, the Agreement.

2. PROVISION OF DATA ACCESS

- 2.1. AIFS has agreed to make the Data available to the User for the Project on the terms and conditions set out in this Agreement, subject to AIFS obtaining any approvals that it requires in relation to that Data from third parties.
- 2.2. The User has agreed to use and protect the Data on the terms and conditions set out in this Agreement, including any Special Conditions set out in Item 3 of Schedule 1 of The Agreement.
- 2.3. If any conflict arises between the terms and conditions of this Agreement and the Special Conditions, the Special Conditions will prevail to the extent of any inconsistency.
- 2.4. The User acknowledges that the Specified Personnel will access the Data through the Australian Data Archive (**ADA**) and that AIFS has no responsibility for the ADA. The Specified Personnel must comply with any terms and conditions applicable to the ADA when accessing the Data.
- 2.5. For the avoidance of doubt, the parties acknowledge that the Data does not include any data relating to the Medicare Benefits Scheme, the Pharmaceutical Benefits Scheme, Repatriation Pharmaceutical Benefits Scheme; or otherwise collected by any Commonwealth agency; or information contained in other health services records or registers including for chronic conditions, dialysis, transplants, disabilities and infectious diseases. If the User wishes to access such data, the User must seek

approval from the relevant government agencies and any access to that data will be dealt with via a separate agreement.

3. AIFS RIGHTS

- 3.1. Nothing in the Agreement prevents AIFS from exploiting the Data or distributing the Data to any third party.

4. PROTECTION OF THE DATA

- 4.1. The User will:
- a. use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement, including by ensuring Data is stored on password protected computers or electronic devices that are accessible only by the Specified Personnel.
 - b. store all electronic files, the Data and copies of the Data in accordance with the NHMRC Guidelines (Australian Code for the Responsible Conduct of Research).
 - c. develop, implement, maintain and use appropriate administrative, technical and physical safeguards to preserve the integrity and confidentiality of and to prevent non-permitted or violating use or disclosure of any Data which is transmitted electronically. The User will document these safeguards and keep these safeguards current.
 - d. mitigate, to the extent practicable, any harmful effect that is known to the User of a use or disclosure of any Data by the User in violation of the requirements of the Agreement.
 - e. report to AIFS, in writing, any use and/or disclosure of the Data that is not permitted or required by this Agreement of which the User becomes aware. Such a report shall be made as soon as reasonably possible but in no event more than five (5) Business Days after discovery by the User of such unauthorised use or disclosure. This reporting obligation shall include breaches by the User, the Specified Personnel, the User's employees, subcontractors and agents. Each such report of a breach must:
 - i. identify the nature of the non-permitted or violating use or disclosure;
 - ii. identify the Data used or disclosed;
 - iii. identify who made the non-permitted or violating use or disclosure;
 - iv. identify who received the non-permitted or violating use or disclosure;
 - v. identify what corrective action the User took or will take to prevent further non-permitted or violating uses or disclosures;
 - vi. identify what the User did or will do to mitigate any harmful effect of the non-permitted or violating use or disclosure; and
 - vii. provide such other information as AIFS may request.

- f. not identify or attempt to identify the individuals whose information appears in the Data. The User will not contact or attempt to contact the individuals whose information appears in the Data.
- g. allow AIFS, or a representative of AIFS, during ordinary business hours and upon reasonable notice, to attend the premises of the User for the purpose of auditing compliance with the Agreement. The User, Specified Personnel, the User's employees, agents and sub-contractors must give all reasonable assistance to any person authorised by AIFS to undertake an audit in accordance with this sub-clause.
- h. provide AIFS with a copy of valuable or important syntax files (relating to derived variables) to enable replication or verification of outputs for future researchers.
- i. on completion of the Project for which the Data is provided, delete all Data and any Datasets, including new variables created by manipulating the Data, by reformatting or rewriting the Data. The User will confirm in writing to AIFS that the deletion of the Data has occurred.

5. USE OF THE DATA

5.1. The User:

- a. must only use the Data for the purposes of the Project;
- b. must only allow access to the Data by the Specified Personnel;
- c. must not use the Data or Derivatives for diagnosis or treatment purposes in humans;
- d. must comply with all applicable Federal, State and local laws and appropriate standards in relation to the use of the Data including, but not limited to, privacy laws and regulations;
- e. must ensure that all necessary and relevant ethics clearances and regulatory approvals are in place for the Project before using the Data, comply with such approvals at all times, and provide evidence of such approvals to AIFS, if requested to do so;
- f. must treat the Data as Confidential Information of AIFS;
- g. must not use the Data for any profit making or commercial purposes;
- h. must meet any costs incurred by the User related to the access to and release of the Data to the User;
- i. accepts sole responsibility and liability for User's use the Data and Derivatives, will use the Data and Derivatives at its own risk, and must obtain and maintain adequate insurance in respect of its use of the Data and Derivatives;
- j. indemnifies AIFS and its officers, employees, subcontractors 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 User's handling, use and disposal of the Data and Derivatives or a breach of this Agreement by the User;

- k. acknowledges and agrees that to the extent permitted by law, AIFS excludes all warranties, express or implied, including without limitation warranties of merchantability, fitness for a particular use, safety or quality in relation to the supply of the Data. AIFS makes no representation and provides no warranty that the use of the Data will not infringe any patent or other Intellectual Property right of any other person;
- l. at the expiration or termination of this Agreement and at its own cost, dispose of or destroy all remaining Data by reformatting or rewriting or as instructed by AIFS; and
- m. provide AIFS with reports on the progress of the Project and use of the Data bi-annually, and on completion of the Project. AIFS may, from time to time, notify the User of specific issues to be addressed in any reports and the User will address these issues in its reports.

5.2. The User must not:

- a. use the Data for the purpose of reporting on or showing the Data in a form that is likely to identify an individual or an organisation;
- b. perform any matching, sharing, merging or linkage of any of the Data with any other data, without the prior written consent of AIFS;
- c. publish or disseminate, in any form, any part of the Data including at an organisational (e.g. school, medical provider) or individual level;
- d. assign its rights under the Agreement;
- e. transfer, sell, disseminate, disclose or otherwise distribute the Data to any person or third party other than Specified Personnel without AIFS' prior written consent;
- f. use AIFS' name or logo without the prior written consent of AIFS.

6. INTELLECTUAL PROPERTY

6.1. The User acknowledges that:

- a. the Data and any Intellectual Property subsisting in, or in relation to, the Data is the property of the Commonwealth; and
- b. AIFS is responsible for managing access to the Data.

6.2. AIFS grants the User a non-exclusive, royalty-free, non-transferable licence to use the Data for the Project only between the Commencement Date and the End Date.

6.3. Ownership of any Derivatives will be determined in good faith depending upon the proportion of each Party's relative contributions to their development. Notwithstanding

the foregoing, and as between the Parties, the Derivatives shall be owned by AIFS to the extent that the Derivatives incorporate the Data or AIFS's Confidential Information.

- 6.4. To the extent that the User owns the Derivatives, the User grants AIFS a sub-licensable, non-exclusive, worldwide, irrevocable, perpetual, royalty-free licence to use the Derivatives for non-commercial purposes, including teaching, research, and publication. For the avoidance of doubt, this includes a licence to house Data Derivatives owned by the User with the Australian Data Archives, and to sub-licence use of Derivatives owned by the User to third parties.
- 6.5. To the extent that AIFS owns the Data Derivatives, AIFS grants the User a non-exclusive, non-transferable, royalty-free licence to use the Data Derivatives for the User's internal non-commercial purposes.

7. STUDY MATERIALS

- 7.1. Some of the material included or referred to in the study materials (e.g., data dictionary, study questionnaires) is subject to the copyright. Copyright information will progressively be added to these materials.
- 7.2. Users should ensure that they seek and obtain the appropriate copyright permissions from the owner of any copyright material in study materials prior to use.
- 7.3. AIFS is not responsible for obtaining or assisting the User with obtaining copyright permissions.

8. LIABILITY

- 8.1. AIFS does not guarantee the accuracy, currency or completeness of any copyright information in the *Ten to Men* documents.
- 8.2. AIFS accepts no legal liability in relation to any use of the material included or referred to in the study materials.

9. PUBLICATION

- 9.1. AIFS acknowledges that the User and the Specified Personnel may wish to publish or otherwise publicly disclose results generated using the Data or secondary analysis of the Data ('**Publication**'). Publication by the User and the Specified Personnel is subject to the terms of this Agreement, (including those relating to confidentiality and IP).
- 9.2. The User and the Specified Personnel must acknowledge the contribution of the Commonwealth and AIFS in any Publication. Unless otherwise agreed in advance by AIFS in writing, the acknowledgment must be in the form set out in Item 4 of Schedule 1 of the Agreement.
- 9.3. It is acknowledged that research conducted for the purpose of internal administration of Australian Government agencies or for confidential business purposes of the Australian

Government is not always made public, and in such instances would be exempt from clauses 9.3 and 9.4.

- 9.4. The User acknowledges that AIFS may publish details of the User, Specified Personnel and the Project at <http://www.tentomen.org.au/index.php/Researchers/approved.html>

10. CONFIDENTIALITY

- 10.1. Prior to receiving or being provided with access to any Confidential Information, the Specified Personnel must each complete the Deed of Confidentiality and Acknowledgment at Schedule 3 to the Agreement and provide the completed Deed of Confidentiality and Acknowledgment to AIFS.
- 10.2. When receiving Confidential Information, the User must:
- a. keep all Confidential Information of AIFS confidential unless strictly required otherwise by law;
 - b. limit access to the Specified Personnel;
 - c. not use the Confidential Information in any way other than for the Project or as otherwise contemplated by the Agreement without the prior written permission of AIFS;
 - d. ensure that all Specified Personnel to whom the Confidential Information is disclosed are bound to keep the Confidential Information confidential and not to use the Confidential Information except for the Project; and
 - e. immediately notify AIFS of any disclosure required by law and provide all assistance and co-operation which AIFS reasonably requires to seek a protective order or other relief from disclosure.
- 10.3. At any time upon the written request of AIFS, the User must, at its own expense, promptly destroy or return to AIFS any documents which embody AIFS' Confidential Information. The User may retain:
- a. one copy of the foregoing documents, with the exception of the Datasets and Derivatives that can disclose an individual or information regarding an individual, in a secure location for record-keeping purposes only; and
 - b. copies of the foregoing documents, with the exception of the Datasets and Derivatives that can disclose an individual or information regarding an individual, to the extent required by law.

11. CONFLICT OF INTEREST

- 11.1. In this clause 11.1 'Conflict' means any matter, circumstance, interest, or activity affecting the User, its Specified Personnel, employees or subcontractors which may or

may appear to impair the ability of the User to deal with the Data diligently and independently.

- 11.2. The User warrants that, to the best of its knowledge after making diligent inquiry, at the Commencement Date no Conflict exists or is likely to arise in relation to its receipt or use of the Datasets.
- 11.3. If, during the Term a Conflict arises, or appears likely to arise, the User agrees:
- a. to notify AIFS immediately;
 - b. to make full disclosure of all relevant information relating to the Conflict; and
 - c. to take any steps AIFS reasonably requires to resolve or otherwise deal with the Conflict.

12. OBLIGATIONS OF THE USER IN RELATION TO PRIVACY

- 12.1. The User agrees, in accessing the Data:
- a. to comply with its obligations under the Privacy Act and not to otherwise do any act or engage in any practice which, if done or engaged in by AIFS, would be a breach of an Australian Privacy Principle under the Privacy Act; and
 - b. to comply with any directions, guidelines, determinations or recommendations provided by AIFS to the extent that they are consistent with the obligations referred to in clause 12.1.a.
- 12.2. If the User becomes aware that there are reasonable grounds to suspect that there may have been an Eligible Data Breach in relation to any Personal Information held by the User as a result of the Agreement or its access to the Data, the User agrees to:
- a. notify the AIFS in writing as soon as possible, which must be no later than within 3 days; and
 - b. unless otherwise directed by the AIFS, carry out an assessment in accordance with the requirements of the Privacy Act.
- 12.3. Where the User is aware that there are reasonable grounds to believe there has been, or where AIFS notifies the User that there has been, an Eligible Data Breach in relation to any Personal Information held by the User as a result of the Agreement or its access to the Data, the User must:
- a. take all reasonable action to mitigate the risk of the Eligible Data Breach causing serious harm to any of the individuals to whom it relates;
 - b. unless otherwise directed by AIFS, take all other action necessary to comply with the requirements of the Privacy Act; and
 - c. take any other action as reasonably directed by AIFS.

- 12.4. The User agrees to notify AIFS immediately if it becomes aware of a breach or possible breach of any of its obligations under this clause 122.

13. TERM AND TERMINATION

- 13.1. The Agreement commences on the Commencement Date and, unless extended or terminated earlier in the manner set out in the Agreement, will remain in effect for the Term.
- 13.2. The User may, thirty (30) days before the End Date, request in writing up to two 12 month extensions to the Term of the Agreement. Any request for an extension of the Term must include a progress report which includes a justification for the proposed extension of the Term. Reasonable extensions requested in accordance with this clause will be approved by AIFS
- 13.3. Any extensions in addition to the two 12 month extensions to the Term in clause 13.2 are at the discretion of AIFS.
- 13.4. A Party may terminate the Agreement if the other Party is in default of the terms and conditions of the Agreement and fails to take action to remedy the default within 30 days after receiving a Notice from the Party requiring the remedy of the default.
- 13.5. AIFS may terminate the Agreement if reports provided in accordance with clause 5.1.m indicate that no progress in relation to the Project is being made in the two years after the Commencement Date.
- 13.6. AIFS may terminate the Agreement at any time without giving cause by giving the User 30 days' notice.

14. GENERAL CLAUSES

14.1. Tax

The User must pay all taxes imposed or levied in Australia or overseas in connection with the performance of the Agreement.

14.2. Severability

If anything in the Agreement is void or otherwise unenforceable then it will be severed and the rest of the Agreement remains in force.

14.3. Waiver

Any waiver or amendment of any provision of the Agreement will be effective only if in writing and signed by an authorised representative of both Parties.

14.4. Assignment or novation

The User shall not assign or novate the Agreement at all without the written permission of AIFS.

14.5. Relationship of the Parties

The User is not by virtue of the Agreement an agent, partner or employee of AIFS. The User agrees:

- a. not to misrepresent its relationship with AIFS; and
- b. not to engage in any misleading or deceptive conduct in relation to the Project.

14.6. Entire agreement

Each Party will take such steps, execute all such documents and do all such acts and things as may be reasonably required by any other party to give effect to any of the transactions contemplated by the Agreement.

14.7. Variation

The provisions of the Agreement will not be varied either in law or in equity except by agreement in writing signed by the Parties. AIFS reserves the right to change these Terms at any time, effective upon the posting of modified Terms. Such changes will be notified via email.

14.8. Governing law and jurisdiction

The Agreement is governed by, and is to be construed in accordance with the law in force in the state of Victoria and the Parties submit to the non-exclusive jurisdiction of the courts of the State of Victoria.