



Australian Longitudinal Study on Women's Health:

The University of Newcastle and The University of Queensland

POLICY AND PROCEDURES FOR DATA ACCESS, ANALYSIS AND PUBLICATION

I. Ownership and Access to ALSWH Data

1. Data collected by researchers associated with the Australian Longitudinal Study on Women's Health (ALSWH) are held in trust by the University of Newcastle and the University of Queensland.
2. Data may be made available to collaborating researchers where there is a formal request to make use of the material. Collaborators may request to either analyse ALSWH survey data and/or conduct a substudy of the ALSWH participants. For both, permission must be first obtained from the Data Access Committee of ALSWH.
3. A request for access to survey data for analysis (Expression of Interest (Eoi)) must be made electronically to the Data Access Committee of ALSWH (see the [online Eoi form](#)). The request should include the following information:
 - Project leader's name, institution and email
 - Name of ALSWH Liaison person. It is a requirement that a member of the core ALSWH team be involved as a Liaison person on every analysis (see Section III - Role of ALSWH Liaison Person). Collaborators must contact an ALSWH Liaison person to discuss their project prior to submission of the Eoi. A list of current ALSWH Liaison people is available at <http://www.alswh.org.au/who-is-involved/alswh-liaison>
 - Names of all other people working on the project. All people working with the data must read the Privacy Protocol and sign the Confidentiality Statement. Collaborators are only required to sign one Confidentiality Statement which remains current for any future projects. A Statement of Data Use (see Document D) must be signed for each approved Eoi
 - Title of potential project
 - Details on student projects
 - Whether this study involves linked data
 - Whether the EOI supersedes/updates previous Eoi
 - 100 word lay summary of proposed project
 - Rationale, hypotheses, main variables of interest (*Variable details can found at <http://www.alswh.org.au/for-researchers/data>*) and proposed analysis plan
 - Expected outputs (papers, PhD, conference papers, further grant applications etc)
 - Time frame
 - Budget and source of funds

- Names and addresses of all people who will have access to the raw data
- Names of people who will provide the substantive expertise and input
- Names of people who will advise and/or carry out the statistical analysis
- Keywords
- Applicable themes
- Survey datasets required
- Other datasets required (MBS, PBS, National Death Index (NDI), Aged Care Data, Perinatal, Cancer registry and Admitted Patients Data Collections). See section II (Access to Other Data).

Student projects. Please follow the Eol procedure as for non-student projects – further information is available here <http://www.alswh.org.au/how-to-access-the-data/alswh-data>. A student must be listed as lead collaborator on an Eol where the majority of the project will contribute to the student's award. Students must provide updates on their project when requested every six months.

In addition, please advise ALSWH of:

- Any change of supervisor/s or course
 - Expected submission date
 - When completed please advise the date of award for thesis/degree etc
 - Upon completion ALSWH must be provided with a short summary of the student project. A lay summary is preferred, but a thesis abstract is acceptable
 - Students should check the intellectual property guidelines for the university/institution before commencing work on ALSWH projects.
5. Requests may be made to ALSWH to conduct a substudy of the ALSWH women (a substudy involves recruiting a sample of the ALSWH women and inviting them to participate in a smaller research project on a specific topic). See <http://www.alswh.org.au/how-to-access-the-data/alswh-data> for how to request permission to conduct a substudy of ALSWH women (Document C). Separate ethical approval from the researcher's home institution or other Human Research Ethics Committee is required before a substudy will be approved by the ALSWH Data Access Committee.
6. Requests for access to data or to conduct a substudy are considered by the Data Access Committee. If approved, the data are provided specifically for the analysis described in the request. This approval includes any reasonable minor and related changes and additions that arise during the course of the work. However, please note:
- a. The ALSWH must be notified of any substantial changes to the nature of the analysis, the topic addressed, or requested datasets by submitting a new Eol application form and noting the amendment/s. Such amendments require approval by the Data Access Committee before they are undertaken.
 - b. Minor changes, such as changes to the collaborators involved or updating the dataset with a more recent survey, do not require a new Eol application form but can be advised by emailing ALSWH sph-wha@sph.uq.edu.au

Lead collaborators on an approved Eol will be requested to provide six monthly progress reports. If no progress has been made after two update requests then the project approval may be withdrawn.

7. A Statement of Data Use (Document D) and signed a Confidentiality Statement (see Document E: Privacy Protocol) must be signed by any person associated with the project including those who present results, or whose name appears on a publication which is associated with the project. Data

will not be provided until these documents are signed.

8. In signing the Statement of Data Use the lead collaborator acknowledges responsibility for ensuring adequate facilities and resources to enable the project to progress in a reasonable manner.
9. Details of EoIs previously conducted using ALSWH data may be made available to other researchers seeking access to ALSWH data. Details will only be released once the research from the previous EoI is completed or the EoI is terminated or made inactive.
10. Full acknowledgement of the source of data used must be provided in any publications that arise from access to and use of the data as set out in section V.5 (Guidelines to Publication and Conference Presentations).
11. Where substudy data have been collected by an individual researcher, or are regarded as of primary interest to that researcher, and are made available to a second scholar, the original researcher, if available, should be invited to participate in any publications that follow from use of the data. The original researcher is not bound to accept co-authorship.

Requests may only be made to access ALSWH substudy data when the substudy is completed and it is not intended that the data be used for any further publications under the substudy.

12. Numerical survey data will be continually edited, and those who are responsible for the data (see section 1.1) are obliged to ensure that the data are regularly reviewed and edited. Publications should use the most up-to-date information available, and should include the date and source of all data used in any publication.

II. Access to Other Data

The ALSWH has gained approval to access a number of National and State-based external data sets (MBS, PBS, National Death Index, Aged Care Datasets, Perinatal, Cancer registry and Admitted Patients Data Collections) and these de-identified data can be linked with ALSWH data to provide researchers with an expanded ability to investigate the health of Australian women.

1. Various State and Federal Privacy Acts govern the use of administrative datasets in addition to the usual ethics regulations. Research teams using linked datasets are therefore legally and ethically bound to comply with all rules as detailed below, in addition to the usual Human Research Ethics Committee requirements. Accessing administrative datasets for research purposes is a privilege that will be revoked should any member of the research team contravene these rules.
2. Access to external linked de-identified datasets such as those noted above may be made available to collaborating researchers where there is a formal request to make use of the material. Permission to use the data must be obtained from the Data Access and Data Linkage Committees (DLC) of ALSWH and all relevant data custodians and ethics departments.

A request for access to linked datasets for analysis (Expression of Interest (EoI)) must be made electronically to the Data Access Committee of ALSWH. Please follow the EoI procedure as for projects requesting only ALSWH data. In addition, please complete the relevant ALSWH Data Linkage variable request form. This form can be accessed through the [online EoI form](#) or via the [website](#).

3. Although the ALSWH has received approval from data custodians and relevant Human Research Ethics Committees to access data from external linked datasets, anyone who requires access to these data need to check with their ALSWH liaison person who will either confirm that they are currently approved, or will arrange for appropriate applications to be submitted. Depending on the circumstances and the number of datasets involved, this process may incur an administrative fee which will be ascertained on a case by case basis.
4. Analyses on external linked datasets may only be conducted at the University of Queensland, the University of Newcastle or through the SURE facility at the Sax Institute <https://www.saxinstitute.org.au/our-work/sure/> . If external researchers wish to include external linked data in analyses, they may opt for one of the following:
 - The researcher may conduct analyses on site at either the University of Queensland or the University of Newcastle. This option is dependent on the availability of facilities and resources at the time of request.
 - ALSWH will provide an experienced statistician to conduct analyses on behalf of the researcher. This option will involve a cost recovery which will be negotiated on a case by case basis, based on the complexity of work involved. It is also dependent on the availability of resources.
 - Researchers may opt to use the SURE facility. If this option is chosen, researchers are responsible for any costs imposed by SURE to access the data.
5. After all collaborators who will have access to these linked data have approval from all applicable Data Custodians and relevant Human Research Ethics Committees, and approval is granted by the Data Access and Data Linkage Committees, the Data Linkage administrative assistant will send all necessary documentation to the research collaborators (i.e. ALSWH Statement of Data Use and ALSWH Confidentiality Statement, and any similar documentation required by other Data Custodians).
6. De-identified data are provided specifically for the analysis described in the request, including any reasonable minor changes and additions that arise during the course of the work. This approval is for a period of two years from date of receipt of the data. At the end of the two year period the following guidelines apply:
 - a. If no work has progressed and/or no publications have been submitted the researchers may apply to the ALSWH Data Access Committee for an extension (with justification) of approval of the project OR the data must be destroyed in accordance with the following requirements. All data including any duplicate copies, or other copies created through manipulation of the original data, must be deleted, physically destroyed or rendered irrecoverable in accordance with NHMRC guidelines contained in the Australian Code for Responsible Conduct of Research (<http://www.nhmrc.gov.au/guidelines/publications/r39>). All electronic files must be permanently deleted from the computer server. All paper documents must be shredded or disposed of in a locked security bin. All files stored on any CDs, DVDs, media devices must be unlocked and permanently deleted. **Note that this clause does not apply to data derived from external datasets (linked data) which are never to be stored on any electronic device except University of Newcastle or University of Queensland secure computers (please see below for conditions of use of linked data).**
 - b. If work has progressed or is in progress the researchers may apply to the ALSWH Data Access Committee for an extension (with justification) of approval of the project. Any

substantial changes to the nature of the analysis or the topic addressed require an updated or new request.

- c. If the work is completed and/or publications have been submitted the researchers must keep the data in accordance with NHMRC guidelines contained in the Australian Code for Responsible Conduct of Research.
- d. Researchers provide a certificate of destruction of data if the project ceases prior to completion or, if it does, the data goes to ALSWH for secure electronic archiving.

It is a condition of use that linked data are not transferred via the internet, email or copied to a USB memory stick, laptop or to other removable media.

7. In signing any Statement of Data Use documents, the lead collaborator acknowledges responsibility for ensuring adequate facilities and resources to enable the project to progress in a reasonable manner. The lead collaborator will be asked for regular updates to monitor progress. Non-completion of any requested update will result in the project not being included in any Reports for that period. Repeated non-completion of progress reports may result in the project being cancelled.
8. Full acknowledgement of the source of data used must be provided in any publications that arise from access to and use of the data as set out in V.5 (Guidelines to Publication and Conference Presentations).

III. Role of ALSWH Liaison Person

1. On each EoI, collaborators must nominate an ALSWH Liaison person who will provide oversight and advice for the EoI (A list of current ALSWH Liaison people is available at:<http://www.alswh.org.au/who-is-involved/alswh-liaison>). ALSWH Liaison people are very familiar with ALSWH data as well as the areas of research currently being conducted using the data. Therefore they are able to provide advice regarding the feasibility of any prospective projects. ALSWH projects involving access to external data sets must include a Liaison person who has experience using these data.
2. Please note: The research team MUST discuss the EoI with the Liaison person and allow them to review it before it is submitted to the Data Access Committee. EoIs that do not meet this requirement will be returned for revisions.
3. The responsibility of an ALSWH Liaison person is limited to the following:
 - Discussing the EoI application with the potential collaborator/s
 - Providing advice on developing the research plan (including appropriate use of ALSWH data)
 - Maintaining contact with the lead collaborator for the duration of the project
 - Reviewing reports, abstracts for conferences and manuscripts before they are submitted to a journal. (The ALSWH Liaison person reserves the right to refer publications to the Data Access Committee).
4. In addition to these liaison responsibilities, the Liaison person's level of involvement with the project must be discussed prior to the project commencing. It is expected that the Liaison person will be included as a collaborator and an author on papers consistent with their contribution to the project - please see the NHMRC guidelines for detail:
http://www.nhmrc.gov.au/files_nhmrc/file/publications/synopses/r39.pdf

5. If the Liaison person agrees to collaborate on the project they should be listed on the Eol application in the 'ALSWH liaison' field as well as the 'Other Collaborators' field.

IV. Guidelines to Analysis

1. Data analysis must be conducted according to recognised standards. Collaborators should familiarize themselves with the datasets, the Notes for Collaborators using ALSWH Data and data from external datasets, the Data Dictionary, and the Data Dictionary Supplement, all of which are available from: <http://www.alswh.org.au/for-researchers/data>. We strongly recommend that researchers use ALSWH derived variables where they exist. These variables are derived following standard methods and/or guidelines, and in most cases, are validated. Researchers should therefore be careful if they choose to treat variables differently. When using ALSWH qualitative data, researchers must follow the qualitative data protocols, available from <http://www.alswh.org.au/how-to-access-the-data/alswh-data>.
2. Individual comments are appropriately used in qualitative research. It is imperative that individual comments should not make it possible for a participant to be recognised. When using individual comments, researchers must:
 - a. Use false names, if names are used
 - b. Change specific details such as numbers and ages of children, and precise details of diagnosed conditions, family circumstances, employment details, or other identifying characteristics. These should be altered in a way which does not substantially alter the point being made but which disguises the actual participant and her circumstances
 - c. Indicate clearly in all written and verbal presentations that specific details have been changed to avoid recognition of individuals

V. Guidelines to Publication and Conference Presentations

1. The lead collaborator must take overall responsibility for publications. Publications and journal submissions must be reviewed by the ALSWH liaison person before submission to a journal or editor. The ALSWH liaison person reserves the right to refer publications to the Data Access Committee.
2. Publication of multiple papers based on the same set(s) or subset (s) of data is improper unless full cross-referencing occurs within the papers, for example, by reference to a preliminary publication at the time of publication of the complete work which grew from it.
3. Researchers should follow their institutions guides as well as NHMRC guidelines pertaining to publications and conference presentations. The current NHMRC Australian Code for the Responsible Conduct of Research can be found at <http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>.
4. There will be no honorary or courtesy authorship; ie. no person may be listed as author when he/she has not participated in a substantial way in conceiving and/or executing and/or interpreting at least part of the work described in the publication.
5. All publications (including those using data from external datasets linked with ALSWH data) must include the following acknowledgement:

"The research on which this (paper, book, monograph, abstract or report) is based was conducted as part of the Australian Longitudinal Study on Women's Health by the University of

Queensland and the University of Newcastle. We are grateful to the Australian Government Department of Health for funding and to the women who provided the survey data”.

6. Where Medicare or Pharmaceutical Benefits Scheme (PBS) data are used, The Department of Health and Medicare Australia must be acknowledged with the statement “We acknowledge the Department of Health and Medicare Australia for providing the PBS and MBS data. We also acknowledge the Australian Institute of Health and Welfare (AIHW) as the integrating authority for these data”.
7. Where the food frequency questionnaire has been used, Cancer Council Victoria must be acknowledged with the statement "The authors thank Professor Graham Giles of the Cancer Epidemiology Centre of Cancer Council Victoria, for permission to use the Dietary Questionnaire for Epidemiological Studies (Version 2), Melbourne: Cancer Council Victoria, 1996." Furthermore, all parties are to notify each other before presenting any DQES data at a conference, seminar or other forum, and, where appropriate, must provide copies of the presentation, papers etc. to the Director of the Cancer Epidemiology Centre.
8. Where Participant Status (National Death Index) data have been used, the AIHW must be acknowledged with the statement “We acknowledge the assistance of the Data Linkage Unit at the Australian Institute of Health and Welfare (AIHW) for undertaking the data linkage to the National Death Index (NDI).”
9. Where Aged Care Data are used, the Department of Health and the AIHW must be acknowledged with the statement “We acknowledge the Department of Health for providing these data and the AIHW as the integrating authority and the source of the data”.
10. Where data from other external sources are used, the following acknowledgement with appropriate insertions, should also be included
 - For NSW data: “The authors thank the NSW Ministry of Health, the NSW Central Cancer Registry and staff at the Centre for Health Record Linkage (CHeReL)”.
 - For Victoria: “The authors thank staff at The Cancer Council Victoria”.
 - For QLD, WA and SA Data: “The authors wish to thank the staff at the [*Insert name of Data Linkage Unit/s*] and the data custodians of the [*insert names of Data Collections involved*]”.
11. Any outcome/s from research using data from external datasets must be reviewed/ approved by the ALSWH DLC and the ALSWH liaison person before they are circulated beyond the collaborators named in the EoI.
12. a) Collaborators who have used data from the following external state-based datasets must provide a copy of all publications to the relevant data linkage unit prior to submission.

WA- Hospital Morbidity Data System (HMDS), WA Cancer Registry and Midwives Notification System (MNS)

NSW- Admitted Patients Data Collection (APDC), NSW Cancer Registry and Perinatal Data Collection (PDC)

QLD- Admitted Patients Data Collection (QHAPDC), Queensland Cancer Registry (QCR) and Queensland Perinatal Data Collection (QPDC)

SA- Hospital Morbidity Data System (HMDS) and South Australian Cancer Registry (SACR)

b) Papers based on data provided by the AIHW (MBS, PBS, Aged Care, NDI) must be provided to the AIHW, but these do not need to be reviewed prior to publication.

13. Additional funding agencies should also be acknowledged if this is applicable.
14. The acknowledgement may refer to any other persons who have provided comments, advice, support or other input into the paper, who are not already listed as authors. Permission should be sought from these persons before including their names.
15. Due recognition of all participants is part of the proper research process. Authors should ensure that research assistants, technical officers, and other 'non-authors' who contribute, including community members involved in supporting the project, are properly acknowledged.
16. Authors must provide copies of manuscripts or reports and all correspondence to ALSWH when the paper/report is submitted, reviewed, re-submitted and finally accepted. A hard or electronic copy of the published Paper should be provided to ALSWH.
17. Authors must provide all details of conference presentations to ALSWH. This correspondence should occur when the abstract has been submitted.