



PRIVACY PROTOCOL FOR AUSTRALIAN LONGITUDINAL STUDY ON WOMEN'S HEALTH (ALSWH)

The Australian Longitudinal Study on Women's Health (ALSWH), managed by the Research Centre for Gender, Health and Ageing (RCGHA) at the University of Newcastle and the University of Queensland, collects data on the health of Australian women in three age cohorts. Around 40,000 women have agreed to participate in the project and have provided personal and health information on survey forms. This information is currently held in hard copy and electronic form at the University of Newcastle and in electronic form at the University of Queensland. Complete data sets are archived with the Social Sciences Data Archive at the Australian National University. Many of these women have also provided consent for the project team to access their Medicare records, and this information is stored in hard copy and electronically at ALSWH at the University of Newcastle.

This Privacy Protocol should be read and the Confidentiality Statement signed by all people who have access to ALSWH data, databases, surveys or identifying information. The Privacy Protocol should be retained and the Confidentiality Statement returned to ALSWH before the commencement of the project.

A. General Principles

The conduct of the project must comply with the Information Privacy Principles set out in Section 14 of the Privacy Act 1988. The Principles concern the collection, solicitation, security, use and disclosure of personal information. Any person who has access to any personal information pertaining to the project participants must be made aware of, and undertake in writing to abide by the Information Privacy Principles, and the National Privacy Principles contained in the 2000 Amendment to the Act. Copies of these documents are available on the Privacy Commissioner's website at <http://www.privacy.gov.au/>

Data obtained for this research project (including personal details and survey responses) will only be used for those purposes as specified in the funding agreement between the Commonwealth of Australia and the University of Newcastle and the University of Queensland.

Access to data is permitted only for approved research purposes, and data may not be used for any other purpose or passed on to third parties.

This document contains three subsections in the Practical Guidelines section:

1. For people conducting secondary analyses;
2. For people conducting substudies;
3. For people working with surveys, consent forms and personal identifiers.

Your ALSWH liaison person will direct you to the appropriate sections for you to read. You must also read the documents "Policy and Procedures for Data Access, Analysis and Publication" (Document B) and "Procedures for Substudies" (Document C). Special protocols apply to the analysis of the ALSWH qualitative data. Researchers wishing to use ALSWH qualitative data should refer to the qualitative data protocols available from <http://www.alsw.org.au/accessingdata.html>.

B. Practical Guidelines

1 For people conducting secondary analyses.

- (a) Approval to conduct an analysis must be sought from the Data Access Committee before data are obtained. Approval is for analysis on a specific topic and other analyses may not be conducted without seeking further approval.
- (b) Electronic files of survey data are available after the Confidentiality Statement and Statement Governing the Analysis, Use and Publication of Data have been signed. The data should be obtained from the ALSWH Data Manager at The University of Queensland, and not from other sources, to ensure that the most up-to-date data are provided. Copies of datasets previously provided by ALSWH for other analyses conducted by the collaborator must not be used.
- (c) Identifiers. Data files will contain a study ID which is unique and must be used to link data sets. Names and personal information are not included.
- (d) Storage of electronic files. Project leader and approved collaborators, who have read the Privacy Protocol and signed the Confidentiality Statement, will be sent an encrypted data file via AARNET's CloudStor. These must be copied to a password-protected area on the project leader's computer or network that is not accessible to others who have not signed the Confidentiality Statement. Copies of the data files may not be made except for the purpose of backup. Any research assistants or project assistants who access the data must read the Privacy Protocol and sign the Confidentiality Statement.
- (e) Completion. The project leader must inform ALSWH once analysis is complete. All data must be removed from computers and networks on which they were stored and archived in accordance with the project leader's research institute guidelines. The CD referred to in (d) must be returned to the ALSWH Data Manager at The University of Queensland once the analysis is complete.
- (f) Confidentiality. Where the results of research using ALSWH data are published or presented in public, information must be presented in a form that does not permit the identification of any individual participant.
- (g) 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.
- (h) Acknowledgement. All publications should contain acknowledgements as outlined in the "Policy and Procedures for Data Access, Analysis and Publication" (Document B).

2 For people conducting substudies

Substudies are managed by ALSWH and the Data Manager Cohorts is responsible for the selection of participants. All consents and personal identification are kept at ALSWH. Contact with substudy participants must be from ALSWH offices, and surveys will be returned to ALSWH University of Newcastle for logging, checking and removal of personal identifiers before being passed on to collaborators. Personal contact details of women selected for substudies will not be available to collaborators working outside of ALSWH offices. Requests from project leaders for release of this information will initially be made on the Substudy EOI (Document H) and should detail why it is essential for the project and how confidentiality will be maintained. Final approval for release must be sought from the University of Newcastle Human Research Ethics Committee.

- (a) Approval. All requests for substudies that involve contacting participants must be submitted to the University of Newcastle Human Research Ethics Committee for approval, after agreement has been reached with ALSWH. This is in addition to all other institutional ethics committees required by ALSWH liaisons or collaborators.

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- (b) Substudy packages are posted from ALSWH at the University of Newcastle or by a data management company contracted to undertake this task by ALSWH University of Newcastle. They will include the study ID, a cover letter with the participant's personal details and a change of details card.
- (c) Completed surveys are returned to ALSWH University of Newcastle, not directly to the ALSWH liaison person. Consent forms are removed before surveys are made available to ALSWH liaisons, and stored in filing cabinets in a locked office at ALSWH. ALSWH liaisons receive surveys with a study ID and without personal contact details
- (d) Telephone surveys will be carried out as follows. ALSWH staff will send letters to potential participants, follow-up procedures will be negotiated between the collaborators/ALSWH liaison and ALSWH in accordance with HREC guidelines. Telephone interviews will then be carried out at ALSWH. Any contact information passed on to the researcher from a participant must be forwarded immediately to ALSWH for processing.
- (e) Deletion. Copies of all data files must be provided to the ALSWH Data Manager at the University of Newcastle for archiving.
- (f) Confidentiality. Where the results of research using ALSWH data are published or presented in public, information must be presented in a form that does not permit the identification of any individual participant.
- (g) Publications and journal submissions must be submitted to the Data Access Committee before submission to a journal or editor. The Data Access Committee will undertake to provide feedback as soon as possible, and at the latest within two weeks. The Data Access Committee does not provide a full internal review but checks for inconsistency in methods, and any apparent misrepresentations of ALSWH
- (h) Acknowledgement. All publications should contain acknowledgements as outlined in the "Policy and Procedures for Data Access, Analysis and Publication" (Document B).

3 For people working with surveys, consent forms, and personal identifiers

(a) *Consent forms and personal identifiers*

- (i) Completed consent forms contain participants' names, personal contact details, IDs and secondary contact details. All completed surveys are returned to ALSWH and consent forms are removed. All consent forms are kept in filing cabinets in a locked office at ALSWH. Access to these cabinets, and use of the data, is permitted only for legitimate research management purposes. The Confidentiality Statement at the end of this document must be signed prior to accessing any of these files. The Deputy Director or the Cohort Data Manager University of Newcastle controls access as required. Consent forms must not leave the office and must be filed when not in use. Information contained on the consent forms must not be divulged to any third party or recorded elsewhere, except as is necessary for legitimate research management purposes within the ALSWH office. Consent forms for women who withdraw from the project are removed from the main filing system and stored in a separate, locked filing cabinet.

Consent forms will be kept until completion of the project, then archived in a secure place until five years after completion of the project.

- (ii) Medicare consent forms were completed by women who consented to access to their Medicare unit records, and contain names, personal contact details and ID. These forms were sent to the Medicare Australia (previously Health Insurance Commission) who maintain them in accordance with their own privacy principles. Photocopies of all Medicare consent forms are kept in a locked store room at the

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University of Newcastle. Access to these is controlled by the Cohort Data Manager or Deputy Director University of Newcastle.

- (iii) Electronic files of consent information, personal identification, and participation status are stored in a password protected database on a network drive which is also password protected. The Cohort Data Manager controls access as required. Copies of these files, or sections of them, may be taken only for the purpose of secure archiving and backup. Where lists of names and addresses are generated, these lists are provided only to staff and external contractors who require them for mailouts and other participant contact. External contractors will delete their copies of all electronic participant contact details once the Cohort Data Manager is satisfied that they are no longer required. Deletion of files will be confirmed in writing to the Cohort Data Manager. Files containing de-identified information on participation status are available to investigators for legitimate research purposes only.

(b) Survey data

- (i) Completed forms. Completed survey forms are checked and logged on receipt at ALSWH. Any identifying information in the body of the survey is erased. The consent form, which includes identifying information, is removed and stored separately (see Section 1). Survey forms are sent to an external contractor for scanning or data entry; the contractor undertakes to maintain confidentiality of all files. Once data are entered in electronic form, a series of data integrity checks are undertaken by the Cohort Data management team under the supervision of the Cohort Data Manager. Once this team is satisfied that the scanned images of the surveys are accurate, the Data Management Group is asked to endorse a decision to destroy the paper surveys. Once the Data Management Group endorses the destruction of the hard copies, the Cohort Data Manager instructs the Data Management company to securely destroy the hardcopies of the surveys in accordance with HREC requirements and as set out in the agreement between ALSWH and the data management company. Imaged surveys are stored electronically in protected files and are kept in a locked store room at the University of Newcastle. Hardcopies of surveys for which electronic images are not stored are kept in locked storage at the University of Newcastle. The Deputy Director University of Newcastle or the Cohort Data Manager will control access of surveys as required. External contractors will delete their copies of all scanned survey data files once the Cohort Data Manager is satisfied that they are no longer required. Deletion of files will be confirmed in writing to the Cohort Data Manager. Completed survey forms must not leave the office or store room and must be locked away when not in use. Individual information contained in the surveys must not be divulged to any third party or recorded elsewhere, except as is necessary for legitimate research purposes.
- (ii) Electronic files of survey data contain the study ID that can be linked to names and addresses only through the consent file or the file of names and addresses. Data files are available to project leaders, who must read the Privacy Protocol and sign the Confidentiality Statement. Contractors responsible for data entry, printing, mailing and scanning will delete their copies of all electronic files once the Cohort Data Manager is satisfied that they are no longer required. Deletion of files will be confirmed in writing to the Cohort Data Manager.

(c) Medicare Unit Record Data

The electronic files contain study ID and Medicare unit record data for those women who have given consent for access to their Medicare data. The research team does not have access to Medicare PINs or card numbers. A confidential file linking study IDs and Medicare PINs is maintained by Medicare Australia (previously the Health Insurance Commission). All electronic files are password protected. Access to these files is controlled by the Data Managers who are delegated by the Directors/Deputy Directors to oversee record linkage.

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(d) Publication of Results

- (i) Proposed 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.
- (ii) Acknowledgement. All publications should contain acknowledgements as outlined in the “Policy and Procedures for Data Access, Analysis and Publication” (Document B).
- (iii) Where the results of research using ALSWH data are published or presented in public, information must be presented in a form which does not permit the identification of any individual participant.

(e) General

- (i) Access to consent forms, survey forms and data files will be granted to authorised personnel by the Deputy Director or Cohort Data Manager at the University of Newcastle. All project leaders and collaborators are required to ensure that personal information (names, addresses and telephone numbers) and data are kept confidential at all times. Staff must be vigilant in ensuring that forms are filed when not in use, and that data files are secure.
- (ii) All members of staff, students and collaborating researchers who are working on the ALSWH project will be required to sign the Confidentiality Statement that they will observe the privacy principles at all times.
- (iii) Any waste paper which has identifying information other than the ID number is to be shredded after use.
- (iiii) Electronic files and original data will be and archived in accordance with NHMRC guidelines, available at <http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>



CONFIDENTIALITY STATEMENT
for the Australian Longitudinal Study on Women's Health

- I have read the documents "Policy and Procedures for Data Access, Analysis and Publication" (Document B) and "Policy and Procedures for Substudies" (Document C) and agree to abide by their conditions.
- I have read the Privacy Protocol (Document E) and agree to abide by its conditions.

Title

Name

Organisation

.....

Email address

Signature **Date**

- Affiliation**
- Collaborator
 - ALSWH staff member
 - Student
 - ALSWH Liaison
 - Consultant / company