

# Australian Longitudinal Study on Women's Health



## ***Australian Longitudinal Study on Women's Health: The University of Newcastle and The University of Queensland***

### **Policies and Procedures for Substudies**

A substudy involves the collection of new data from ALSWH participants. The data collected are usually linked to existing ALSWH data to take advantage of the longitudinal aspects of the project. Substudies place demands on participants and their scientific value must be weighed against the avoidance of over-burdening participants.

Substudies may be conducted by survey (online/postal) or telephone. Telephone interviews can only be conducted from the ALSWH office at the University of Newcastle (UN). Names, addresses and contact numbers will not be released to external groups. In considering approvals for Substudies, the Data Access Committee of the ALSWH considers each of the following principles.

1. Are the aims of the substudy consistent with the overall aims of the ALSWH? The ALSWH participants are not a convenience sample and substudies must be related to policy-relevant health and well-being outcomes.
2. Is the substudy feasible with respect to the researchers involved, logistics of running the substudy, timing of data collection and funding available?
3. Will the outcomes of the substudy be scientifically valid, with respect to the generalisability of the sample and issues such as statistical power?

ALSWH recognises that Research Higher Degree (RHD) students may need to undertake their own data collections. RHD projects will be assessed on a case-by-case basis but at a minimum, RHD students will be expected to undertake data collection at UN under the direct supervision of a member of the ALSWH Operations team. Costs for this type of supervisory support will also need to be taken into consideration and procedures must be prearranged with UN Operations staff and be clearly described in the EoI.

The ALSWH UN office will require cost-recovery reimbursement for all costs associated with organizing and conducting the substudy. Payment must be made to ALSWH UN office at the commencement of the substudy. Researchers must allow for additional costs where

changes are made to substudy requirements that were not included in the quote, or where there is an unforeseen increase in cost to ALSWH in running the substudy.

The following guidelines are provided to assist researchers in preparing an Expression of Interest (Eoi) and conducting substudies. These guidelines should be used together with the accompanying flowcharts, available <http://www.alsw.org.au/how-to-access-the-data/alsw-data>

Please also refer to Document B for detailed data access guidelines.

## Expression of Interest submission dates

There are six Eoi submission dates each year:

- 31 January
- 31 March
- 31 May
- 31 July
- 30 September
- 30 November

The timeline from submission to approval is approximately 2 months.

## Before submitting an Eoi

1. Select an ALSWH liaison person. A list of current ALSWH Liaison people is available at: <http://www.alsw.org.au/who-is-involved/alsw-liaison>. The role of the liaison person is to provide oversight and advice for the substudy concerning the ALSWH data. They are able to provide advice regarding the feasibility of any prospective substudies.
2. Discuss the proposed substudy with your ALSWH liaison person and with the UN ALSWH Deputy Director Deb Loxton.

For queries concerning whether a substudy may overlap or conflict with an existing substudy, please contact either UN ALSWH Deputy Director Deb Loxton or UQ ALSWH Deputy Director Leigh Tooth (details below).

3. Have a meeting or teleconference with the ALSWH Deputy Director at UN, Deb Loxton or her delegate, the ALSWH Operations Manager at UN, Anna Graves and your ALSWH liaison person to determine:
  - Ethical requirements
  - Feasibility of timelines and budget requirements
  - Exclusion/inclusion criteria
4. Complete the online Eoi form for substudies from <http://www.alsw.org.au/how-to-access-the-data/alsw-data>.

The Eoi form should be accompanied by:

- Preliminary copies of all survey/telephone interview questions
- A detailed and agreed budget

The accompanying documentation should be uploaded via the online system using the 'upload document button' at the top of the form.

### **Ethical requirements for substudies**

All substudies must be cleared with Human Research Ethics Committees (HREC) at UN and UQ in addition to any other institutions to which researchers belong. Previous surveys and ethics applications are available from the UN office staff. Sample letters of invitation and consent forms are available from the UN office and it is strongly recommended that you use these as they have been developed over several years of corresponding with participants. Postal/online surveys should be consistent with the familiar ALSWH format and identified as part of ALSWH. This will also assist with clearance from the ethics committee/s.

The final draft of the ethics application and accompanying documentation must be seen and approved by the Operations Manager at UN, Anna Graves, prior to submission to UN HREC, for confirmation of the substudy procedure, timeline and budget.

Once ethical approval has been granted by the relevant HRECs, copies of all ethics approval notifications must be sent to the Operations Manager at UN, Anna Graves. Staff at UN will then forward copies to UQ.

### **Once your EoI is approved**

1. Ensure substudy has received all ethical approvals (as above).
2. Sign the ALSWH Statement of Data Use and Confidentiality Statement and return to UQ.
3. Liaise with designated UN staff to plan implementation of the study. Send UN final copies of all survey/telephone interview questions and documentation.

### **Conducting the substudy**

1. Ensure payment to UN for costs of conducting the substudy.
2. Meet with UN staff to finalise:
  - Exclusion/inclusion criteria
  - Survey/telephone interview questions. If UN staff are to conduct telephone interviews, face to face training of the ALSWH project assistants by the

researcher is required. It is recommended researchers try to anticipate questions which may be asked or might be confusing for participants.

3. At the conclusion of the data collection, the raw dataset and respondent list is to be provided to the ALSWH Database Developer at UN, Ryan Tuckerman, who will replace participant identifiers with an analysis identifier (e.g. IDAlias) and send to the ALSWH Data Manager at UQ, David Fitzgerald.
4. Provide 12 monthly progress reports when requested by the ALSWH. We do not expect substudies to be completed within 12 months but do expect that the substudy will adhere (more or less) to the timeline outlined in the initial proposal. Note: If the substudy does not provide satisfactory reports (particularly after reminders), the Data Access Committee reserves the right to withdraw permission for the substudy.
5. Prior to submission of papers, conference abstracts or reports, cleaned substudy data must be submitted to the ALSWH Database Developer at UN and the ALSWH Data Manager at UQ for archiving.

Archiving ensures the data will be available for others once the original collaborators no longer need the data. Should future persons express interest in using the data, ALSWH will adhere to the current NHMRC guidelines for sharing data and contact the original collaborators and give them the opportunity to liaise and/or collaborate with these persons. The collaborator must confirm in the final substudy progress report that the data have been archived.

6. Any papers, conference abstracts or reports that do not include the ALSWH liaison person as a co-author, must be submitted to the Data Access Committee for comment before they are submitted externally. All publications/presentations must include the standard ALSWH acknowledgement (as outlined in Document B):

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

## **Following completion of the substudy**

1. Final progress report

Collaborators should provide a final progress report. This should include a lay summary of no more than 300 words of the results of the substudy. The ALSWH may include it in the ALSWH Annual Participant Newsletter. If there is an ethics requirement that a participant feedback letter be sent within a different timeframe, individually to

participants or for a different reason, the letter will be sent as required. Otherwise the participant newsletter can serve this function.

Final Reports are also included in the ALSWH Technical and Annual Reports to the Department of Health.

## **ALSWH Contacts**

UN ALSWH Deputy Director Deb Loxton  
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