



Australian Longitudinal Study on Women's Health:

The University of Newcastle and The University of Queensland

PUBLICATIONS, SUBSTUDIES AND ANALYSES COMMITTEE (PSA) 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.

In considering approvals for Substudies, the Publications, Substudies and Analyses committee (PSA) 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?
4. Will the ALSWH team have sufficient resources to fund the ALSWH staff to conduct the sampling and organisation of the postal and/or telephone surveys. For assistance with costing, please contact your ALSWH liaison, or the ALSWH UN office: whasec@newcastle.edu.au

To propose and conduct a substudy

To propose a substudy you will need to nominate an ALSWH liaison person. Your liaison will be an ALSWH Steering Committee member. You will also need a copy of the Substudy Expression of Interest form, available: www.alswh.org.au/accessingdata.html

Then complete the steps included in the following table.

PROCEDURES FOR SUBSTUDIES

Step	Who	Action	Timeframe (working days)	Notes
1	Collaborator	Preparation		Please discuss your proposal informally with the Project Deputy Director, Deb Loxton, or with the Project Coordinator, Leigh Tooth, to identify any conflicts with existing projects before doing too much work. At this time an informal overlap check will be carried out. Also please plan your proposal with your ALSWH liaison person. To avoid overlap with other ALSWH projects, it is essential to read through ALSWH analyses and substudies that have been or are being conducted: http://www.alswh.org.au/substudy_analyses.html
2	Collaborator ALSWH UN and other staff	Preliminary meeting		Hold a preliminary meeting (in person or via teleconference) with ALSWH University of Newcastle (UN) staff. The purpose of this meeting is to determine timelines and budgets for inclusion in your proposal. This is also a good time to discuss your inclusion/exclusion criteria for drawing a subsample.
3	Collaborator			Complete your proposal using the Substudy Expression of Interest form. Please include preliminary copies of any surveys/interviews you are planning to use.
4	Collaborator	Send to the PSA Administration Officer (AO)		
5	PSA AO	Allocate a project ID number. Send to PSA	Within 2 days	

Step	Who	Action	Timeframe (working days)	Notes
6	PSA	Comment and discuss within group, reach decision	Within 14 days	PSA may decide to reject completely, or request modifications and clarifications, or endorse Proposal. Some Substudy Expressions of Interest might need to be reviewed by the Steering Committee, which will involve a short delay with processing.
7	PSA Chair & AO	Convey decision to Collaborator (cc to AO). If endorsed, AO to send MoU (Doc.D), Privacy Protocol (Doc.E).	Within 2 days	
<i>If decision is to reject, exit process here</i>				
<i>If decision is to request modifications and clarifications, repeat from step 3</i>				
<i>If decision is to endorse, go to step 8</i>				
8	Collaborator and ALSWH liaison	Re-read relevant guidelines and Privacy Protocol, and sign MoU (Doc.D) and confidentiality statement (Doc.E).	Within 10 days	
9	Collaborator	Finalise survey/ interview materials, letters to participants etc, and ethics applications for all relevant institutions. Send to Deputy Director (UN), Deb Loxton.	Normally within 1 month	Previous surveys and ethics applications are available from the Newcastle office staff. Sample letters of invitation, consent forms and change of details cards are available from the Newcastle office and it is strongly recommended that you use these as they have been developed over several years of corresponding with participants. 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. All projects must be cleared with Human Research Ethics Committees at the Universities of Newcastle and Queensland, in addition to any other institutions to which collaborators belong.
10	Deputy Director (UN), Deb Loxton	Circulate survey materials to ALSWH UN staff for proofing/comments	Within 2 days	

Step	Who	Action	Timeframe (working days)	Notes
11	ALSWH UN staff	Provide feedback on survey materials and timing	Within 10 days	
12	Collaborator	Finalise survey materials and methods	Normally within 1 month	
13	Collaborator & Data Manager (Cohorts)	Finalise inclusion/exclusion criteria and draw sample	Normally within 1 month	This will be an iterative process of revision and discussion, which is very important.
14	Collaborator	Obtain ethics clearance from all relevant institutions, provide copies of applications and materials to ALSWH UN office		Make sure you are aware of due dates, months when ethics committees do not meet, and other things that may slow the process down. Substantive changes to content or methods should be discussed with the Deputy Director (UN), Deb Loxton. Copies of all paperwork should be provided to the ALSWH office. Ethics clearance forms in particular must be provided. Delays at this stage may be unavoidable, and may affect the feasibility of the entire substudy. Please keep everyone informed!
15	Collaborator	Provide information to ALSWH research staff on substudy protocols etc. Collaborate with RA to work on substudy in ALSWH office		
16	ALSWH UN staff and UN RA	Draw sample Final layouts Printing Post surveys or make phone calls	Within 1 month of receiving final materials and approvals	This is all done in close collaboration with the Collaborator. It is strongly recommended that the Collaborator meet personally with staff and if possible spend time in the office while the substudy is under way. If telephone interviews are to be undertaken, then face to face meetings between the researchers and the interviewers must take place.

Step	Who	Action	Timeframe (working days)	Notes
17	ALSWH UN staff & RA	Log returns Remove & file consent forms Track RTS Enter Change of Details Staff 1800 number Conduct reminders	As in timeline	Prepare an information sheet for staff based at ALSWH UN who will receive participant phone calls and requests for assistance. Try to anticipate questions which may be asked or might be confusing for participants.
18	Collaborator	Inform UN RA, on a weekly basis, any changes in participant status including change of details etc.		
19	ALSWH RA	Provide collected material (surveys, tapes) to Collaborator	As timetabled	
20	Collaborator	Enter and clean data, analyse, write up	Normally within 6 months of receipt of data	It is expected that you will need to communicate with ALSWH data and statistics staff who will provide information if requested. Any papers, conference abstracts or reports that do not include a member of the Steering Committee as a co-author, must be submitted to the PSA AO for distribution to the PSA for comment before they are submitted externally.
21	Collaborator	Destroy any hardcopies of names and addresses and delete electronic files of names and addresses. Return surveys, tapes or other study materials to ALSWH for secure storage. Report back to ALSWH UN with a summary of findings to be published in the participant newsletter.	On completion of project	

Step	Who	Action	Timeframe (working days)	Notes
22	Collaborator	Report to PSA (through AO) on progress, outputs and plans.	Within 6 months of endorsement of Proposal	<p>Collaborators will be expected to provide a progress report at around the 6-month mark. If you do not provide a report, after a reminder, it will be assumed you have abandoned the project.</p> <p>We do not expect substudies to be completed within 6 months but do expect that you will stick (more or less) to the timeline outlined in your initial Proposal.</p> <p>If a substudy has fallen more than two months behind the timeline provided in the Proposal, the feasibility of the project will be reassessed by the Deputy Director (UN) and brought to the attention of the PSA if necessary.</p>
23	Collaborator	Feedback letters to substudy participants	On completion of project	Collaborators should provide ALSWH with a lay summary of no more than 300 words of the results of the substudy. The ALSWH will include these in the ALSWH Annual Newsletter unless there is an ethics requirement that a participant feedback letter be sent within a different timeframe, individually to participants or for a different reason.
24	PSA	Review progress	Six monthly	At this stage, the PSA can decide (a) project is finished – no action needed (b) the project has not made sufficient progress and can be assumed to be abandoned (c) the project is progressing satisfactorily
25	Collaborator	Submit substudy data to ALSWH for Archiving.	Upon completion of substudy	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 contact the original collaborators and give them the opportunity to liaise and/or collaborate with these persons.
<p><i>If project has made little progress or is seriously behind schedule, and cannot be rescheduled satisfactorily, the PSA may withdraw approval. The main study data must be deleted from the computer and deletion verified in writing to the data managers (see Step 21) and any substudy data collected must be submitted to ALSWH for archiving (see Step 25).</i></p>				
<p><i>If project is progressing satisfactorily but not yet completed, continue and report again in 6 months</i></p>				