Sub-Study Overview

The North West Adelaide Health Study (NWAHS) is an representative longitudinal study of approximately 4000 adults originally recruited from the northern and western regions of Adelaide during 2000 and 2002/03. Its core activity is to provide longitudinal self-reported and measured data to assist in maximising the effectiveness of strategies for the prevention, early detection, and management of chronic conditions.

The NWAHS welcomes the interest and proposals of external investigators. Collaboration is encouraged as it helps to maximise the scientific value of the epidemiological data made possible by the participation of more than 4000 individuals in the North West Adelaide Health Study. In order to facilitate access and ensure the optimal scientific outcome, the NWAHS requires the following procedures.

An sub-study is an investigation which is beyond the core aspects of the NWAHS but uses NWAHS participants, including samples or data collected by the NWAHS. Examples include studies funded by investigator-initiated research awards (such as NHMRC), grants from academic institutions, or those performed at no additional cost (generally because of the special interest of a researcher). Sub-studies may involve the collection of new data from participants, or testing or analyses of previously collected data (incl biosamples, images or other sources, eg Medicare data).

Approval for a sub-study will be given on the proviso that the investigators agree to return the complete sub-study dataset to the NWAHS.

Types of Sub-Studies (SS)

The NWAHS recognises four main types of sub-studies:

**SS1:** Those imposing a new burden on the study participants, seeking funding from government, foundation, industry or other sources (called participant burden/outside funded studies) and/or requesting biosamples other than DNA;

**SS2:** Those involving genetic specimens (called DNA studies);

**SS3:** Other research projects, usually small in magnitude (where funding already exists, is minimal or is not needed) – requests for data from individual researchers may only be required to complete a Data Agreement form and related scientific proposal, depending on the nature of the request;

**SS4:** Those involving data from outside NWAHS repositories (eg data linkage with data from other agencies, ie hospital admission or early childhood records).

Each of these classes of sub-studies has a different and distinct review and approval mechanism. Investigators proposing sub-studies should review the following to determine exactly which type of sub-study corresponds to their proposed study. Special attention should be given to the required submission procedures and required timing of the proposal.

**SUBMISSION AND REVIEW PROCESS**

**Necessary approvals**

The NWAHS Management Committee must approve all sub-study proposals. In addition, depending on the type of sub-study, other committees and agencies may be involved in the approval process. A chief investigator of the NWAHS must be included in the project and approval obtained from The Queen Elizabeth Hospital Ethics Committee before the project will be approved to commence.
Submission process and proposal forms

The investigator should determine the specific type of study being proposed from one of following three types of studies:

- SS1 Sub-study proposals involving participant burden, outside funding and/or biosamples;
- SS2 DNA and genetic analysis;
- SS3 Minor research projects (with no or minimal funding, may only require existing data).

Guidelines are still being developed for projects requiring data linkage.

The sub-study application form is attached to these guidelines. The investigator should follow the directions and complete all forms including supplementary and supportive materials as stated in the instructions. The proposal applications often require materials in addition to completion of a proposal form. All required materials should be completed and the application submitted to the NWAHS contact designated on the application form.

Review criteria

For all types of sub-studies and at each level of review, highest priority will be given to studies that:

- do not interfere with the main NWAHS objectives;
- have the highest scientific merit;
- produce the smallest burden on NWAHS participants and the least demand on NWAHS resources;
- require the unique characteristics of the NWAHS cohort.

In addition, priority for studies requesting biological samples will be highest if they:

- do not make use of samples from those participants with the fewest samples;
- assays desired can be done on more than one sample type to allow selection of the most abundant type available;
- use the smallest sample volume possible; evidence of attempts to minimise volumes will be examined by the NWAHS Management Committee;
- can be integrated with other studies to conserve sample or limit freeze-thaw cycles.

Priorities will also need to be determined in terms of the NWAHS biomedical priorities, existing and proposed NWAHS biomedical studies, and the perceived value of any medical test requested by researchers. This may also mean how a requested test fits with priorities and/or adds value to NWAHS data.

The Management Committee will consider participant burden in determining approval, and the proposed study must:

- be acceptable to the participants (eg time, discomfort, privacy);
- not interfere with other parts of the Study;
- not hamper continued participation in the main Study;
- put minimal demand on scarce Study resources;
- require the unique characteristics of Study cohort(s);
- meet requirements of the highest scientific merit.

The investigators must have adequate resources (including ethics approval and sufficient budget) to effectively complete the project, and their staff must have the requisite expertise to meet the objectives of the project.

Additional documents to be developed include more detailed guidelines for sub-studies regarding:

- the conduct of the study (participant burden, study proposal, resources required, confidentiality agreement, provision of final sub-study dataset to main study);
- publication policy (submission of manuscripts for review, authorship).
### Sub-Study Agreed Terms & Conditions

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The Sub-Study investigators agree to:

1. Include a chief investigator of the NWAHS in the project.

2. Provide evidence of appropriate ethics approval from The Queen Elizabeth Hospital Ethics Committee.

3. Limit the research project to that described within the Sub-Study Proposal – which should detail the aims, hypotheses to be tested, significance, background and research plan (including details of methods to be used, considerations of statistical analysis and power, and references where relevant).

4. Protect the privacy and confidentiality of the cohort participants and related survey subjects.

5. Provide a new amended Sub-Study Agreed Terms & Conditions document if either substantive changes made to the designated research project or the appointment of another researcher to complete the research project.

6. Acknowledge the contribution of the North West Adelaide Health Study (NWAHS) Chief and Associate Investigators, together with that of the study participants and research, clinic and recruiting staff, in any and all oral and written presentations, disclosures and publications resulting from any or all analyses resulting from the sub-study data, using the paragraph below:

   This manuscript has been reviewed for scientific content and consistency of data interpretation by chief investigators of the North West Adelaide Health (NWAH) Study. The NWAH Study team are most grateful for the generosity of the cohort participants in the giving of their time and effort to the study. The NWAH study team also is very appreciative of the work of the clinic, recruiting and research support staff for their substantial contribution to the success of the study.

7. Provide a copy of all manuscripts (or other disclosure documents, such as media releases) to a NWAHS chief investigator at least thirty (30) days prior to submission for publication or release, in order to ensure compliance this agreement. The North West Adelaide Health Study should be mentioned in the title, abstract and/or keywords of all publications using NWAHS data and/or participants. A copy of all such publications will be held in the study’s central register of publications.
8. Retain control over all NWAHS data and further agrees not to transfer the data, with or without charge, to any other entity or individual.

9. Pay any fees required - the NWAHS does not generally charge for requests for sub-studies; however this may need to be negotiated on an individual basis, including for any data analysis.

10. Provide security for NWAHS-related sub-study material so that it is not accessible by anyone who does not also have authorised access.

11. Provide the NWAHS with a report on the sub-study’s outcome.

12. Provide the NWAHS with a copy of all additional data collected on cohort participants and related survey subjects, according to agreed guidelines on formatting, etc.

The NWAHS may terminate this Sub-Study Agreement if the recipient is in default of any condition of this agreement and such default has not been remedied within thirty (30) days after the date of written notice of such default by the NWAHS.

**Signature** Principal Investigator:

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Approval by (name of Chief Investigator):

CI Signature:

Date:

The signed completed Sub-Study Agreement and the Scientific Proposal should be lodged with the NWAH Study Co-ordinator, Janet Grant (fax 8226 6244) or pdf document by email to Janet.Grant@health.sa.gov.au

Enquiries may be directed to NWAH Study Co-ordinator on (tel) 8226 6054.