



PROCEDURE: ETHICAL REVIEW PROCEDURES

Research reviewed by other SA Health institutions

Research Ethics Committees within the SA Health public framework have agreed that ethical review conducted by one of the committees will be accepted by another committee without further ethical or scientific review. These processes may be applied to both research which is normally subject to review by the full committee and research which is of low and negligible risk and has previously been managed through expedited processes.

The Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) requires:

- The Participant Information Sheet to include a heading that indicates that the research is being conducted at the applicable CALHN site. SA Health letterhead or dual badged letterhead is preferred.
- The Participant Information Sheet to include a providing contact details for the CALHN. The preferred statement is:

“If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Central Adelaide Local Health Network Human Research Ethics Committee on 8222 4139.”

Research approved under these guidelines will be listed on the agenda of the next HREC meeting for information.

Research to be conducted at other SA Health institutions

The CALHN HREC will review studies to be conducted at CALHN and other SA Health Institutions. It is expected that where research is conducted at multiple SA Health Sites, the Ethics Committee responsible for the primary review will be the committee that services the Institution of the main investigator – to be known as the Coordinating Principal Investigator (CPI).

Research reviewed by other institutions

The NHMRC have established a framework to facilitate the ethical review of research conducted at multiple sites throughout Australia. See the CALHN HREC Policy regarding Ethical Review of Multicentre Research for further information.

Application procedures for studies submitted to CALHN HREC

If a study is to be conducted at one of either Royal Adelaide Hospital, The Queen Elizabeth Hospital or SA Pathology (IMVS campus) and not at other SA Health Institutions, it is considered as a single site submission. If a study is to be conducted at Central Adelaide Local Health Network and secondarily at other sites within SA Health, it is considered a multi-site submission. In respect to submission to the CALHN HREC, the requirements for both types of studies are the same.

SA Health has mandated that all research conducted within SA Health Institutions be entered into a database called AU-RED. A portal for Investigators to submit to this database is provided through a website called “On-line forms” available at www.ethicsform.org/au. If a study will require committee review it must be submitted through on-line forms which requires completion of the Human Research Ethics Application (HREA) form. All applications undergoing full committee review will also require the completion of a site-specific assessment form (SSA) which is also available through on-line forms. Instructions for submission are on the on-line forms website. In brief the application requires:

- Establishing a user account
- Completing the HREA (note that a HREA provided by the sponsor or from another site may be imported and modified for local applicability).
- Completion and submission to on-line forms of the other required documents listed in the Form - CALHN HREC required submission documents (see Appendix 1).
- When complete the application must be submitted and a submission code obtained.
- The submission code must be provided to the Executive Officer of the Ethics Committee – Note that until this is communicated to the Ethics Office, the office does not know that a submission has been made.
- Completion of the SSA process which links to the Ethics Application through the submission number and the HREC application number.

Application procedures for studies submitted elsewhere

If a study is to be conducted at multiple sites within SA Health the submission should be made to the site of the CPI and an SSA completed at all sites at which the study is being done. The local committee application guidelines should be followed for determination of additional documents required for each committee. The CALHN HREC does not require an ethics application but a SSA must be completed.

Application procedures Low and Negligible Risk Research

Low and negligible risk research should be submitted to the CALHN HREC using the existing processes. . shown in Appendix 1.

Application procedures Audits

SA Health have agreed that audits do not need to be submitted through on-line forms or entered into AU-RED. Applications should be submitted to the CALHN Research Office. The Chairperson will decide whether the application can be classified as an audit.

Revision history

Version 1.0 November 2017 – amalgamation of RAH REC and Human Research Ethics Committee (TQEH/LMH/MH) to Central Adelaide Local Health Network HREC