



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 RAH HREC requires:

- The Patient Information Sheet to include a heading that indicates that the research is being conducted at the RAH. RAH letterhead or dual badged letterhead is preferred.
- The Patient Information Sheet to include a providing contact details for the RAH HREC. 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, Research Ethics Committee, Royal Adelaide Hospital 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 Royal Adelaide Hospital Research Ethics Committee will review studies to be conducted at the Royal Adelaide Hospital 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. The National Approach (previously called HoMER – Harmonisation of Multicentre Ethical review) is not yet implemented within South Australia.

Application procedures for studies submitted to RAH

If a study is to be conducted at RAH 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 RAH and secondarily at other sites within SA Health, it is considered a multi-site submission. In respect to submission to the RAH ethics committee, 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 National Ethics Application Form (NEAF). 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 NEAF (note that a NEAF 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. A list of the required documents is included in the document "RAH required submission documents" on this web site.
- 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 RAH does not require an ethics application but an SSA must be completed and the Executive Officer of HREC should be advised.

Application procedures for Low and Negligible Risk Research

SA Health are developing a process for on-line submission of low and negligible risk research studies which will be based upon procedures in place in New South Wales. A checklist will be provided to assist the researcher to determine whether the research is suitable for this process. If in doubt, researchers should call the Executive Officer of the committee. At present low and negligible risk research should be submitted to the RAH committee using the existing processes. A site specific assessment process must be completed for all low and negligible research which has resource or indemnity implications. A list of required documents is shown in the document "RAH required submission documents" on this web site.

Application procedures for 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 Executive Officer of the committee. The Chairman will decide whether the application can be classified as an audit.

Revision history

Version 1.0 A Thornton 6 February 2010
Version 2.0 A Thornton 29 June 2012