



PROCEDURE

Ethical & Governance Review of Research

Sydney Adventist Hospital Human Research Ethics Committee

Step 1:

Before initiating any research please refer to [Ethical Review of Research: A Practice Guide](#). The Guide contains a *Research Checklist & Authorisation* which must be completed as the first step in governance and ethical review.

Step 2:

Where the [Research Checklist](#) identifies that further ethical review is required, contact the Research Governance & Ethics Officer to discuss the appropriate application method.

Jenelle Quick
ethics@sah.org.au
Phone: 0417 042 300

Step 3:

Where the *Research Checklist* identifies that the [Research Proposal: Risk Assessment](#) is to be submitted to the HREC, complete the form and submit with all the required documentation together with the completed *Research Checklist & Authorisation*.

Step 4:

For research which is a clinical trial of a drug / device, evidence of scientific review must be provided. Research which has received ethical and scientific approval by a NSW Health Lead HREC may have already undergone scientific review. A copy of the HREC letter of approval must be submitted with the application. Where no scientific approval is available, contact the HREC to discuss how scientific review is to be provided. Costs associated with certification will be borne by the Sponsor.

Step 5:

Where the Checklist identifies that an Application for Ethical Review must be submitted to the HREC, complete the *NSW Health NEAF and SSA Form*. Forms can be found at <http://www.ethicsform.org/Au/SignIn.aspx>. Where the application is for multi-centre research, the NEAF approved by a NSW Health Lead HREC should be submitted with a SSA Form for Sydney Adventist Hospital

Please ensure that when completing SSA Form Point 9 *Departments and Services involved in research* and Point 10 *Study Budget* that all departments /services that will be utilised in conducting the research are listed and costed this includes but is not limited to:

- Staff education or training
- Additional nursing care
- Investigations which are not part of routine care
- Use of pathology personnel, equipment and/or services such as centrifugation of samples, storage of specimens, access to the department.

The final budget must present a realistic cost of conducting the research and how these costs will be met. You must consult the Nursing Executive Officer, Director of Pathology and/or other departmental directors to obtain an accurate cost analysis.

Please Note: The only signature required on the SSA Form is that of the Principal Investigator. No other signatures are required.

Step 6:

1. Please provide all supporting documentation identified by the NEAF. Refer to [Supporting Documentation Checklist](#) for site specific details of requirements for the Clinical Trial Agreement, Indemnity, Insurance and other documents.

2. The Participant Information Sheet (PIS) must comply with the NSW Health Standardized Patient Information Sheets. Refer to

http://www.health.nsw.gov.au/policies/gl/2007/GL2007_016.html

- A version number and page numbering must be included
- The HREC contact for complaints about the ethical conduct of research should be identified as follows:

Research Ethics Officer
Sydney Adventist Hospital Human Research Ethics Committee
Phone: 0417 042 300 or Email: ethics@sah.org.au

3. Multiple copies of documents must be submitted as follows:

- **1 copy** of NSW Health Lead HREC letter of approval indicating scientific approval
- **1 copy** of Certification of Scientific Review where NSW Health Lead HREC approval is not available
- **1 original** NEAF signed by the Principal Investigator/s. Please clearly identify which document is the **original**. For multi-centre research submit a copy of the NEAF approved by a NSW Health Lead HREC.
- **1 original** SSA Form signed by the Principal Investigator/s. No signatures of departmental heads are required. Please clearly identify which document is the **original**.
- **10 copies** of the NEAF and SSA Form
- **10 copies** of Participant Information & Consent
- **Also submit** the Participant Information & Consent as a Microsoft Word compatible document by email to ethics@sah.org.au
- **10 copies** of any other documents e.g. questionnaires, advertising
- **1 copy** of an Investigator's Brochure, if applicable
- **1 copy** of Clinical Protocol, if applicable
- **1 original** Form of Indemnity for **each** study site, if applicable
- **3 original (4 originals for ARI funded research)** Clinical Trial Research Agreement signed by sponsor and principal investigator
- **1 copy** insurance Certificate of Currency
- **1 original** CTN Form listing all study sites

NB: Only applications which contain **all** the required documentation will be submitted for governance and ethical review.

Step 7:

Fees are payable to the HREC for submitting research applications for review. Where an application requires submission of a Site Specific Form a fee for Research Governance Review is payable in addition to the fee for Ethical Review.

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A Tax Invoice will be issued upon receipt of the application. Fees are non-refundable, even if an application is unsuccessful or is withdrawn prior to consideration or determination by the HREC. The fees are outlined in the [Fee Schedule](#).

Step 8:

Check the schedule of [meeting dates](#) which contains the application closing dates. For applications to be considered at a Committee meeting, applications must be received by 5pm on the appropriate closing date.

Step 9:

All submissions must be delivered to the following address:

Jenelle Quick
Research Governance & Ethics Officer
Sydney Adventist Hospital
Human Research Ethics Committee
185 Fox Valley Road
WAHROONGA NSW 2076

To ensure timely receipt of your documents please contact the officer, Jenelle Quick on (m) 0417 042 300 to advise when documents are to be hand delivered.