



## GUIDE TO SUBMITTING RESEARCH FOR REVIEW Ethical & Governance Review of Research Sydney Adventist Hospital Group

### **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 ethical and governance review.

### **Step 2:**

Where the [Research Checklist](#) identifies that further ethical review is required, forward the completed form with the study protocol, Lead HREC letter of approval and Participant Information Sheet by email to the Research Governance & Ethics Officer [ethics@sah.org.au](mailto:ethics@sah.org.au) for further advice. If you wish to discuss your submission in person please phone Jenelle Quick on (m) 0417 042 300.

### **Step 3:**

Where the [Research Checklist](#) identifies that a full application must be submitted, evidence of scientific review must be provided. Research which has received ethical approval by a NSW Health Lead HREC or NHMRC Certified 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 4:**

Where the [Checklist](#) identifies that an [Application for Ethical Review](#) must be submitted to the HREC, complete the **NHMRC NEAF and NSW Health SSA Form**. Forms can be found at <http://www.ethicsform.org/Au/SignIn.aspx>. Where the submission involves multi-centre research which has already received single-ethical review, the approved NEAF should be submitted with a SSA Form for each site within the Sydney Adventist Hospital Group.

Please ensure that when completing Point 9 of the SSA Form *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 5:**

1. Please provide all supporting documentation identified by the NEAF and 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](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 Governance & Ethics Officer  
Sydney Adventist Hospital Group  
Phone: 0417 042 300 or Email: [ethics@sah.org.au](mailto:ethics@sah.org.au)

3. **13 collated bundles** of documents which include the following must be submitted:
  - NSW Health Lead HREC or NHMRC Certified HREC letter of approval indicating scientific approval
  - Certification of Scientific Review where NSW Health Lead HREC approval is not available
  - NEAF signed by the Principal Investigator/s. Please clearly identify which document is the **original**. For multi-centre research which has undergone single-ethical review, submit a **copy** of the NEAF approved by a NSW Health Lead HREC or NHMRC Certified HREC.
  - SSA Form (see note below)
  - Participant Information & Consent.
  - All other documents e.g. questionnaires, advertising, data sheets etc
  - Investigator's Brochure
  - Clinical Protocol

*In addition submit the following:*

- **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
- **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**.
- All documents which are submitted must be forwarded as Microsoft Word compatible files by email to [ethics@sah.org.au](mailto:ethics@sah.org.au)

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

**Step 6:**

Fees are payable to the HREC for review of a research submission. 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.

A Tax Invoice will be issued upon receipt of the submission. 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 7:**

Check the schedule of [meeting dates](#) which contains the submission closing dates. For research to be considered at the next Committee meeting, submissions must be received by 8am on the appropriate closing date.

**Step 8:**

All submissions must be delivered to the following address:

Jenelle Quick  
Research Governance & Ethics Officer  
Sydney Adventist Hospital Group  
c/o Australasian Research Institute Building  
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.