

## SUPPORTING DOCUMENTATION CHECKLIST V200808w

### **Clinical Research / Clinical Trial**

The following checklist provides a guide to the documents that **must** be submitted with an Application for Ethical Review to the Sydney Adventist Hospital Human Research Ethics Committee (HREC)

- ❑ **Phase I Clinical drug and/or device trials.** Following submission of an application for a Phase I trial the Research Ethics Officer will forward the application to the Director of Risk Management for review prior to governance and ethical review.
- ❑ **Certification of Scientific Review.** Scientific review accepted from NSW Health Lead HREC, SSAC, CTX Scheme, ARI
- ❑ **Clinical Trial Research Agreement** (Medicines Australia Standard Form) issued without amendment. Changes must be included in Schedule 7.  
<http://www.medicinesaustralia.com.au/pages/images/MA%20Medicines%20Australia%20Model%20Clinical%20Trial%20Research%20Agreement.pdf>

**NB:** Other forms of Agreement will require additional review.

- ❑ Details of the Parties
  - Institution Name: Sydney Adventist Hospital Ltd
  - Address: 185 Fox Valley Road, Wahroonga NSW 2076
  - ABN: 76 096 452 925
  - Contact for Notices: Research Governance & Ethics Officer  
Sydney Adventist Hospital Human Research Ethics Committee
  - Fax for Notices: +61 2 9487 9615
  - Phone No: +61 417 042 300
  - Sponsor: Commercial sponsor must be an Australian corporate entity
- ❑ **Schedule 1 Study Sites**

All study sites are to be listed

  - ❑ Sydney Adventist Hospital, 185 Fox Valley Road, Wahroonga NSW 2076
  - ❑ San Clinic, 185 Fox Valley Road, Wahroonga NSW 2076
  - ❑ Other sites: e.g. Dr's Rooms other than San Clinic, San Ultrasound for Women, Radiation Oncology, Northern Nuclear Medicine, Sydney Haematology and Oncology Clinic (SHOC)
- ❑ **Schedule 2 Payments**

A Schedule of Payments must be included.

  - ❑ All payments for research, except exempt departments, must be deposited to the Hospital's main account:  
Bank: Westpac, 1-3 Rohini Street, Turrumurra 2074  
Account Name: Sydney Adventist Hospital Ltd  
BSB: 032 089 Account No: 000010  
Swift Code: WPACAU25  
Reference: short name of trial / sponsors name / trust cost centre, if applicable
- ❑ **Schedule 3 Form of Indemnity**
  - ❑ **Standard Form of Indemnity for Clinical Trials** (Medicines Australia) without amendment.  
<http://www.medicinesaustralia.com.au/pages/images/Form%20of%20Indemnity.doc>
  - ❑ **Standard Form of Indemnity HREC Review Only** (Medicines Australia) if project is not being conducted at SAH and only ethical review is provided  
<http://www.medicinesaustralia.com.au/pages/images/Form%20of%20Indemnity%20HREC%20Only%20version%20230507B.doc>
  - ❑ Indemnity must be provided by an Australian corporate entity with an ABN
  - ❑ A separate Form of Indemnity is required for each indemnified party as listed in Study Sites Schedule 1 with details of the Parties are to be listed as for Clinical Trial Research Agreement

**NB:** Other forms of Indemnity which are submitted will require additional review.

**Schedule 4 Insurance Arrangements**

Certificates of currency for public / products liability insurance are to be provided on the standard ACORD Certificate of Currency.

Other certificates of insurance must conform to the following criteria:

- List Type of Insurance i.e. Clinical Trials Insurance
- List country i.e. evidence that conduct of the clinical trial in Australia is covered
- Specifically name the Australian corporate entity acting as commercial sponsor. Must be identical to that shown as the sponsor on the CTN Form and on the Form of Indemnity
- Name the insurer/s
- Provide a policy number/s
- Evidence that insurance is available
  - If a Trial Period Policy (preferred) the policy must show that insurance will be current throughout the entire period the trial will be conducted
  - If an Occurrence Policy is provided, and the policy does not cover the entire period of trial, a policy expiration date must be provided
  - If a Claims Made Policy is provided then it must be accompanied by a note for an option to purchase a tail or an extended reporting period AND a retroactive date to demonstrate insurance cover is available for preceding years
- Limits of liability must provide a minimum of AUD\$20M per occurrence and in the annual aggregate. Phase I drug/device trials cover must be negotiated.
- Provide the title of the clinical trial
- Provide the clinical protocol number
- Provide the trial start and end dates
- 30 days notice must be provided to the HREC where an insurance policy is cancelled
- Annual certificates must be forwarded to the HREC
  
- Collaborative research and/or where research is to be conducted at sites in addition to SAH (i.e. San Clinic) Certificate of Currency for Investigator's Medical Malpractice Insurance. Cover must provide a minimum of AUD\$20M for each and every claim and be maintained for the term of the research and 7 years following conclusion. If a claim is made policy, a retroactive date must be included, and annual certificate of currency forwarded to HREC.

**NB:** Certificates of insurance which do not conform to the criteria will require additional review.

**Schedule 5 Guidelines for Compensation for Injury Resulting From Participation in a Company-Sponsored Trial**

**Clinical Protocol**

- Must include a version number and date

**Investigator's Brochure**, if applicable

**Clinical Trial Notification Form (CTN)**

- All sites must be listed as in Schedule 1 of Clinical Trial Research Agreement

**References:** Victorian Managed Insurance Authority *Guidelines for Clinical Trials for Victorian Public Hospitals 2007* [www.vmia.vic.gov.au](http://www.vmia.vic.gov.au)