Checklist for submissions to
SESIAHS Northern Hospital Network
Research Governance Officer

Site Specific Assessments can be submitted at any time on or after the submission of the Ethics Application.

Site Specific Assessment
If the research proposal is being or has been approved by a Lead Ethics Committee please include 1 copy of the documents submitted for Research Ethics Approval and 1 original of the following documents, unless otherwise stated:

Cover Letter
- Outline if study has been or is being considered by the Local or a Lead HREC
- Identify of HREC approval has been granted (include date) or is pending
- List all documents enclosed

Site Specific Assessment Form (SSA) - www.ethicsform.org/au
- Signed and dated by ALL local investigators
- Signed by Head(s) of Department(s) – Principal Investigators who are Heads of Department must not sign their own SSA applications but must obtain the signature of their direct manager.
- Signed by Head(s) of Supporting Department(s) (eg. Pharmacy if dispensing drugs) (if applicable)
- Signed by Data Provision (if applicable)
- Research Governance Officer signature is provided with the recommendation to the Chief Executive Officer’s Delegate
- The Chief Executive Officer’s Delegate signature is the authorisation step.

Short CVs for all Investigators (Principal and Associate) named in the SSA form

Letter of approval from the Lead HREC
Copy of documents as approved by Lead HREC
- NEAF
- Protocol
- Generic Subject Information Statement and Consent Form (each page must have the date and version number in the footer)
- Advertisements, patient diaries, etc
- Investigator Brochure

Study budget fully identified in SSA form

Please note: The SESIAHS Northern Hospital Network incorporates the Prince of Wales Hospital, Royal Hospital for Women, Sydney Children’s Hospital, Sydney / Sydney Eye Hospital, Albion Street Centre, and other public health facilities within the Network. Please check with the Research Governance Coordinator if you are unsure (contact details on page 2)
Clinical Trials

Clinical Trial Notification (CTN) Form

Pharmaceutical/Medical Device Industry Sponsored Studies


Certificate of Insurance ($10,000,000) identifying the research project and period of currency.

Clinical Trial/Study Agreement/Contract between the Sponsor and the Institution (acknowledging the Principal Investigator) on Australian company letterhead. This should be the Medicines Australia Model Clinical Trials Research Agreement (http://www.medicinesaustralia.com.au/pages/page39.asp) which is endorsed by NSW Health. Ensure the legal name of the organisation is used (e.g. South Eastern Sydney Area Health Service – Northern Hospital Network (ABN 78 390 886 131) is the legal entity for POWH, RHW, SCH, Sydney/Sydney Eye Hospital and War Memorial Hospital Waverley). Include the ABNs of both parties. (3 originals)

Specify Name, Address and ABN of Sponsor

Specify Name, Address and ABN of Clinical Research Organisation (CRO) (if applicable)

Indicate whether the Sponsor or CRO is to be invoiced

Other site-specific policy documents required by the Institution

Sydney Children’s Hospital Research Project Resources Clearance Form (must be signed by Head of Department and Head of Directorate and include any relevant supporting documentation)

Enquiries

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