DOCUMENTS REQUIRED FOR NEW SUBMISSIONS

This is a guideline list of Documents and Forms for new study submissions.

Studies requiring Full Committee review, and multi-site Low and Negligible Risk studies must be completed and submitted through **On-line forms**, and forwarded to the CALHN Research Ethics Office by **Electronic pdf format**, by the final date for new Submission.

Low and Negligible Risk studies conducted only at CALHN sites and Audit studies do not need to be submitted through on-line forms, and should be forwarded to the CALHN Research Office in Electronic format only.

Studies Involving an Investigational DRUG (Full Committee review)	
Document Title or Type	**Electronic Copy ONLY**
HREA (through on-line forms only)	**Yes**
Cover letter and Investigator's Statement	**Yes**
Protocol	**Yes**
Informed Consent Documents	**Yes**
Questionnaires	**Yes**
Advertising Material	**Yes**
Investigator's Brochure or Product Information	**Yes**
Drug and Device Checklist	**Yes**
Any other material, including any NMA or State documents	**Yes**
Invoicing and Fee Form	**Yes**
Radiation Safety Report/s (if applicable)	**Yes**
EPA Notification Form (if applicable)	**Yes**
CTN Notification (through TGA electronically)	

Studies Involving a DEVICE (Full Committee review)	
Document Title or Type	**Electronic Copy ONLY**
HREA (through on-line forms only)	**Yes**
Cover letter and Investigator's Statement	**Yes**
Protocol	**Yes**
Informed Consent Documents	**Yes**
Questionnaires	**Yes**
Advertising Material	**Yes**
Investigator's Brochure or Product Information	**Yes**
Drug and Device Checklist	**Yes**
Any other material, including any NMA or State documents	**Yes**
Invoicing and Fee Form	**Yes**
Radiation Safety Report/s (if applicable)	**Yes**
EPA Notification Form (if applicable)	**Yes**
CTN Notification (through TGA electronically)	

OTHER Studies requiring Full Committee review	
Document Title or Type	**Electronic Copy ONLY**
HREA (through on-line forms only)	**Yes**
Cover letter	**Yes**
Protocol	**Yes**
Informed Consent Documents	**Yes**
Questionnaires	**Yes**
Advertising Material	**Yes**
Any other material, including any NMA or State documents	**Yes**
Radiation Safety Report/s (if applicable)	**Yes**
Invoicing and Fee Form *(for Commercial Sponsored or CRG studies)*	**Yes**

Low and Negligible Risk (LNR) Studies	
Document Title or Type	**Electronic Copy ONLY**
LNR Ethics and Governance Application Form	**Yes**
Cover letter	**Yes**
Protocol	**Yes**
Informed Consent Documents	**Yes**
Questionnaires	**Yes**
Advertising Material	**Yes**
Any other material	**Yes**

AUDIT Studies	
Document Title or Type	**Electronic Copy ONLY**
LNR Ethics and Governance Application Form	**Yes**
Cover letter	**Yes**
Protocol	**Yes**
Questionnaires	**Yes**
Data Collection Sheets	**Yes**
Any other material	**Yes**

Before a study can commence the investigator must also complete the governance requirements. Governance requirements may vary depending upon the complexity of the study but will usually include the completion of a Site Specific Assessment form and, for clinical trials a Clinical Trial Agreement. Please consult the Research Governance Officer about these requirements.

Full Committee Review studies to be emailed to: Health.CALHNResearchEthics@sa.gov.au

Low and Negligible Risk and Audit studies to be emailed to: Health.CALHNResearchLNR@sa.gov.au