## Full Site Specific Assessment Form Checklist

This checklist is for applications to obtain authorisation to commence human clinical research study at a site within CALHN when a NEAF/HREA application has been submitted.

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| HREC Reference Number(AU RED) |  | Site Specific AssessmentReference Number |  |
| Principal Investigator |  | Study Coordinator |  |
| Telephone |  | MyIP Number (Office use only) |  |

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| Early SubmissionEarly submission of the draft documents will allow for timely commencement of research governance review which should be conducted in parallel with HREC review.It is only once both HREC and Research Governance applications have been approved that your study can commence in CALHN sites. **The RGO will review and provide a response via email** |
| * Refer to the “Site Specific Assessment Form Guidelines” found at <https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/clinical-trials/> under the “Site Specific Assessment (SSA)” tab.
* Then submit the following items via email to the CALHN Research Office
	+ Draft Research Agreement (Clinical Trial/Investigation or non-standard research study Agreement) (word.doc)
	+ Draft RAH Indemnity Agreement (word.doc)
	+ Budget (draft spreadsheet)
	+ NEAF application or Protocol
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| Final SubmissionSubmit SSA through online forms – a submission code is generated.Please refer to the “Site Specific Assessment Form Guidelines” found at https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/clinical-trials/ under the “Site Specific Assessment (SSA)” tab for additional instructions for online forms.Print SSA form for signing.Ensure SSA code is on each page of the form. |
| * 1) FOR ALL STUDIES, submit the following (via email or ensure they are uploaded in online forms under the ‘Documents’ tab)
	+ Completed cover letter with a list of enclosed and online documents
	+ Copy of the HREC approval letter
	+ SSA Form (1 completed form with signatures/approvals)
	+ Declaration by Associate Investigators and Research Personnel **or** Annual Declaration by Associate Investigators is on file with the CALHN Research Office
* Copy of Biosafety/Chemical/Radiation Safety Approval letters (if applicable – see Q17 of SSA)
* CV for the Principal Investigator (current and no more than 2 pages)
* CV for additional site investigators (current and no more than 2 pages)
* Final site specific Participant Information and Consent Forms for approval
* Final approved Questionnaires, Patient Materials, Diaries, Advertisements etc (if applicable)
* Investigational Drug Subcommittee Report (if applicable)
* Final Study Protocol
* Final NEAF application
* Investigator Brochure and /or product information
* 2) FOR CLINICAL TRIALS INVOLVING INVESTIGATIONAL DRUGS OR DEVICES supported by a Commercial Sponsor/Collaborative Group or CRO, submit the following (with the documents listed in 1 above)
* Medicines Australia Clinical Trial/Medical Technology Association of Australia ‘Investigation Research Agreement’ (3 original copies signed by the Sponsor and Principal Investigator if submitting by hard copy)
* Medicines Australia/Medical Technology Association of Australia ‘Form of Indemnity – Standard’ (3 copies signed by the Sponsor an Principal Investigator if submitted by hard copy – preferably submitted as part of the CTRA/CIRA)
* Certificate of Currency/Insurance
	+ Provision of evidence to CALHN that the Clinical Trial Notification (CTN) Form has been lodged with the TGA
	+ NHMRC Good Practice Process Form - Clinical Trials Feasibility Assessment Information Form ( download from <https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/clinical-trials/> )
* 3) FOR INVESTIGATOR INITIATED CLINICAL TRIALS, submit the following (together in hard/electronic copy with the documents listed in 1 above)
	+ Investigator Initiated Research Agreement (3 copies signed by third party and Principal Investigator if submitted by hard copy)
	+ Research indemnity and insurance approval from Manager Insurance Services
	+ Provision of evidence to CALHN that the Clinical Trial Notification (CTN) Form has been lodged with the TGA
* 4) FOR COLLABORATIVE RESEARCH with third parties, submit the following (together in hard/electronic copy with the documents listed in 1 above)
	+ Collaborative Research Agreement (e.g. grant funded project) (3 original copies if submitting in hard copy)
	+ Research indemnity and insurance approval
* 5) FOR PROVISION OF SERVICES from third parties, submit the following (together in hard/electronic copy with the documents listed in 1 above)
	+ Services Agreement (e.g. provision of staff by University/SAHMRI) (3 original copies if submitting in hard copy)
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| CALHN Research Office:For enquiries and applications please contact the office on:Phone: 82223824Email: Health.CALHNResearchGovernance@sa.gov.auAccess to Online Forms:- <https://au.ethicsform.org>  |