

## NSLHD Submission Checklist - Research Governance - Site Specific Assessment (SSA) For a Greater than Low Risk Research Application

1. The SSA form must be completed within [REGIS](#).
2. All site specific applications must comply with the below checklist – failure to do so may result in an ineligible application.
3. All additional documents to be uploaded in REGIS. Please refer to the [Quick Reference Guides](#) (Project Registration, Site Specific Application - Completing & Submitting, National Mutual Acceptance (NMA) in REGIS).
4. Please [contact](#) the Research Office if you have questions about your research project or application in REGIS, for any technical support, call REGIS Help Desk on 1300 073 447.

### Section 1: SSA Application and Supporting Study Documentation

- Cover Letter** – addressed to the Research Governance Officer (RGO) which lists all documents being submitted including versions and dates, indicates if the application is a student project, addresses any application specific items that you wish to bring to the attention of the RGO, and gives an explanation on why any items listed on the Submission Checklist have not been provided. The cover letter must be signed by the Principal Investigator. [Click here to view a sample cover letter](#)
  - Method of Payment (MoP) Form**  
Applications will not be processed without completed Method of Payment Form.
  - SSA Form**
  - Relevant Departmental Approval/s** – Appropriate head of department support & declaration.  
If the department you are conducting research in is not listed on REGIS, please contact NSLHD Research Office on 02 9926 4590 and advise us of the department name and head of department contact person.
  - Site Specific Participant Information Sheet(s) and Consent Form(s) (PISCF) including version number and version dates** - This is a copy of the Master Participant Information Sheet and Consent Form which includes information pertaining to the site at which the research is to be conducted, e.g. local contact details, (e.g. **Name:** Research Governance Officer, **Email:** [NSLHD-Research@health.nsw.gov.au](mailto:NSLHD-Research@health.nsw.gov.au), **Phone Number:** 02 9926 4590, **NSLHD Reference:** 20XX/STEXXXX), local investigators and [local logos](#) on documentation.
- For projects where the ethics application has been approved outside of REGIS (prior to REGIS implementation or by an HREC outside of NSW and ACT, please also upload the following:**
- HREA** - A copy of the Research application form approved by the HREC.
  - Ethics Approval Letter** - The Ethics Approval Letter from a Lead NSW Health Human Research Ethics Committee (HREC) and any subsequent amendment approval letters (for multi-centre LNR Projects. ***\*The letter/s must list each of the sites at which the study will be undertaken.***
  - HREC Approved Master Participant Information Sheet(s) and Consent Form(s) including version number and version dates**
  - HREC Approved study documentation: protocol, questionnaire(s), survey questions, patient diaries, recruitment advert, interview topics to be covered etc. including version number and date (If applicable)**  
All documents intended for use at a NSLHD site must be submitted with evidence of ethics approval.  
***Please note any documents that will be received and/or viewed by a participant/patient must be made into a site specific format.***

## Section 2 : Departmental Approvals, Funding & Budgets

- Authority for Data Provision** – Please obtain support & declaration from the custodian of the database, within the application (applicable for research activities involving access to paper medical records and/or research projects accessing a database owned by NSLHD).
- Funding Confirmation** – If funding is being provided by an organisation other than NSLHD, written correspondence from the organisation providing funding for the research must be provided.  
*\* Please note funding confirmation is not required when a Clinical Trial Research Agreement (CTRA) is being submitted for the study.*
- Budget** - The budget must reflect the actual costs to complete all of the procedures and administrative tasks of the study. Please include all direct, indirect, and in-kind costs. The budget must be signed by the relevant Management Accountant (Bhavan Sivathondan) or Business Manager (Selin Armutcu) and Head of Department.
- Finance Checklist** - All governance applications submitted to NSLHD research office that include a Clinical Trial Research Agreement (CTRA) must be accompanied a finance checklist. Please refer any queries on completing this checklist to the District Research Business Manager, Selin Armutcu, [Selin.Armutcu@health.nsw.gov.au](mailto:Selin.Armutcu@health.nsw.gov.au)  
*\* Please note the Research Office will obtain Selin’s signature post-submission and you are not required to obtain Selin’s signature prior to submission.  
Please be advised if Bhavan Sivathondan is your management accountant, continue to contact Bhavan for any queries and his signature on the checklist prior to research governance submission.*
- Supporting Department Quotes (may include other departments not listed below)**  
**Pharmacy** - For any studies involving the use of drugs, whether they are approved for the intended indication or not. Pharmacy will be dispensing the drug regardless of the regulatory status of the drug.  
**Pathology** - For any studies engaging the use of Pathology services for a research project.
- External Researcher Information – Site Access and eMR Access**  
Research personnel who are employed by another LHD, University (non NSLHD Researcher) or external organization, and wish to conduct research at any of the NSLHD sites, must submit additional documentation.

## Section 3 : Additional Requirements

### ***Clinical Trials or Research supported by a Commercial or Non-Commercial Sponsor (where applicable)***

- Clinical Trial Research Agreement (CTRA)** – As per [PD2010\\_056](#) all clinical trials with an external sponsor must have a written agreement in place, to clarify the obligations, responsibilities and rights of the parties involved in the research. Five CTRA templates have been approved for use in NSW Public health organisations (PHOs) and can be found [here](#).  
Please note that any clauses included at Schedule 4 or 7 must be approved by the [SEBS Committee](#) and evidence of SEBS approval must be provided with the application.  
Please click here for further information on CTRAs.
- Medicines Australia Form of Indemnity**- For commercially sponsored clinical trials, the sponsor must provide an executed [Medicines Australia Form of Indemnity](#). Please [click here](#) for further information on indemnity forms.
- Certificate of Currency of Insurance** - Commercial sponsors must submit a certificate of currency of insurance that evidences current professional indemnity and products liability policy(s) (or equivalent) and must include clinical trials cover. Please [click here](#) for further information on insurance requirements.

	<input type="checkbox"/> <b>Clinical Trial Notification (CTN) Form</b> -Sponsors completing a CTN involving either the NSLHD HREC or an NSLHD site, relevant details to enter into the CTN are <a href="#">here</a> .
	Investigator Initiated Research including Clinical Trials (NSLHD sponsored)
	<input type="checkbox"/> <b>NSLHD eCTN summary (where applicable)</b> –To be completed for studies in which NSLHD is the sponsor (eg. investigator initiated studies without a collaborative group or pharmaceutical company sponsor). The CTN will be lodged by the Research Office on behalf of the Sponsor (ie. NSLHD), however it is the responsibility of the investigator to provide the information required for the CTN. <input type="checkbox"/> <b>Research Collaboration Agreement</b> - Written agreements for investigator initiated applications are not usually required however in some circumstances, when the research involves an external organisation, an agreement may be requested. Please <a href="#">click here</a> for the further information on Research Collaboration Agreements for investigator initiated research.