### NSLHD Checklist – Site Specific Assessment (SSA)

**For a Multi-Centre Full (Greater than Low Risk) Research Application**

1. **Please note as of 1st March 2019 all Site Specific Applications (SSAs) will only be accepted through the Research Ethics and Governance Information System (REGIS)** [https://regis.health.nsw.gov.au/](https://regis.health.nsw.gov.au/)

2. The SSA form must be completed within REGIS and all additional documents to be uploaded in REGIS only. Please refer to the Quick Reference Guides (Project Registration, Site Specific Application - Completing & Submitting, National Mutual Acceptance (NMA) in REGIS).

3. All supporting documents listed in this checklist are required to be submitted in REGIS only.

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.

5. Incomplete submissions may result in delayed review & will be marked as ineligible within REGIS and the Research Office will require a resubmission of the application.

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

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<tr>
<th>Requirement</th>
<th>Description</th>
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<tr>
<td><strong>Cover Letter</strong></td>
<td>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 study/application specific items that you wish to bring to the attention of the RGO, indicates if the Governance application is being submitted in parallel to NSLHD HREC application 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. <a href="#">Click here to view a sample cover letter</a></td>
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<tr>
<td><strong>SSA Form</strong></td>
<td>The form completed &amp; submitted in REGIS</td>
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<tr>
<td><strong>Relevant Departmental Approval/s</strong></td>
<td>Appropriate head of department support &amp; 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.</td>
</tr>
<tr>
<td><strong>Site Specific Participant Information Sheet(s) and Consent Form(s)</strong></td>
<td>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 undertaken. E.g. local contact telephone numbers, local investigators, local Logo’s on documentation and a local contact for complaints (e.g. RGO) . Please also note the REGIS site application number (e.g 2019/STEXXX)</td>
</tr>
<tr>
<td><strong>Curriculum Vitae (CV)</strong></td>
<td>A short 2 page CV is required for all Investigators listed on the SSA. The CV must include the current position and be signed and dated by the researcher. Once a CV has been provided this is kept on file in the Research Office and linked to all research projects being undertaken by the researcher. CV renewals will be required at a minimum of every two years. In lieu of a CV researchers may wish to submit a declaration of the last submitted CV if this has been in the previous two years.</td>
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For projects ethically approved or submitted for ethics approval from HREC outside of NSW jurisdiction, please also upload the following:

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<tr>
<td><strong>HREA</strong></td>
<td>A copy of the Low Risk Research application form approved by the HREC.</td>
</tr>
<tr>
<td><strong>Ethics Approval Letter</strong></td>
<td>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. <em>The letter/s must list each of the sites at which the study will be undertaken.</em></td>
</tr>
</tbody>
</table>
HREC Approved Master Participant Information Sheet(s) and Consent Form(s) including version number and version dates - If the project is multi-centre please ensure the Master Participant Information Sheet and Consent Form, are provided.

HREC Approved study documentation: protocol, questionnaire(s), survey questions, patient diaries, recruitment advert, interview topics to be covered etc. including version number and version dates - All documents approved for use with the study; which have been listed on the Ethics Approval letter and/or any subsequent Amendment Approval letters.

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 – A copy of written correspondence from the organisation or company providing funding for the research must be provided. If the funding is to be covered by a departmental cost centre written correspondence from the authority of the cost centre must be provided.

Budget
A “Standard” or “Clinical Trial Budget” that reflects the actual costs to complete all of the procedures and administrative tasks of the study. Include all direct and indirect costs, and in-kind costs. A budget is mandatory and must be signed by the relevant Business Manager/Head of Department. (3.3 (iii) NSW MoH PD2010_056).

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 Pack
For research personnel who are employed by another LHD, University (non NSLHD Researcher) or external organization and wish to conduct study activity at any of the NSLHD sites. More information documents require - https://www.nslhd.health.nsw.gov.au/AboutUs/Research/Office/Pages/Not-on-menu/External-Researchers.aspx

Section 3 : Additional Requirements for All Clinical Trials (including Trials involving Investigational Medications or Devices)

Important: 1X NSLHD eCTN summary – 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.

Clinical Trials or Research supported by a Commercial Sponsor (where applicable))

3 x Clinical Trial Research Agreement (CTRA) – Medicines Australia Standard Form/Contract Research Organisation acting as the Sponsor/ Phase 4 or Medical Technology Association of Australia – Standard Clinical Investigation Research Agreement (CIRA - for device trials).
Agreements must be signed by the Sponsor and Principal Investigator before submitting for review.
Schedule 7 conditions should be approved by the Southern and Eastern Border States Process, alternatively these can be sent for external legal review at the Sponsor’s expense.

3 x Medicines Australia Form of Indemnity (Standard) or Medical Technology Association of Australia Form of Indemnity (Standard) between the Sponsor and the NSW Public Health Organisation (PHO).
Agreements must be signed by the Sponsor and Principal Investigator before submitting for review.

1 x Certificate of Currency/Insurance – The policy must meet the requirements of NSW Health Policy PD2011_006 Section 2.2.2

Clinical Trial Notification (CTN) Form - From 1 July 2015, the TGA transitioned to an online system for CTN submission. For sponsors completing a CTN involving either the NSLHD HREC or an NSLHD site, relevant details to enter into the CTN are here.
### Clinical Trials or Research supported by a Collaborative Group (where applicable)

- **3 x Clinical Trial Research Agreement (CTRA)** – Medicines Australia Collaborative or Cooperative Research Group  
  Agreements must be signed by the Sponsor and Principal Investigator before submitting for review.  
  Schedule 4 conditions should be approved by the [Southern and Eastern Border States Process](#), alternatively these can be sent for external legal review at the Sponsor’s expense.

- **3 x Medicines Australia Form of Indemnity (Standard)** between the Sponsor and the NSW Public Health Organisation.  
  Agreements must be signed by the Sponsor and Principal Investigator before submitting for review.  
  or

- **1x Indemnity Assessment** – Investigators who are conducting investigator-initiated clinical trials (Sponsorship responsibilities will be assumed by the LHD) must make an application for consideration of the organisation to accept the indemnity for the trial under Treasury Managed Funds (TMF). The CE is the only one who can bind the use of TMF in this circumstance.

- **Clinical Trial Notification (CTN) Form** - From 1 July 2015, the TGA transitioned to an online system for CTN submission. For sponsors completing a CTN involving either the NSLHD HREC or an NSLHD site, relevant details to enter into the CTN are [here](#).

- **1 x Certificate of Currency/Insurance** – The policy must meet the requirements of NSW Health Policy [PD2011_06 Section 2.3.2 (28)](#).

### Investigator Initiated Clinical Trials (where applicable)

- **1 x Indemnity Assessment** – Investigators who are conducting investigator-initiated clinical trials (Sponsorship responsibilities will be assumed by the LHD) must make an application for consideration of the organisation to accept the indemnity for the trial under Treasury Managed Funds (TMF). The CE is the only one who can bind the use of TMF in this circumstance.