**Research Governance Submission Checklist for Researchers**

This checklist is relevant for the following health services: Western Sydney Local Health District, Northern Sydney Local Health District, The Sydney Children’s Hospital Network, Sydney Local Health District, South Western Sydney Local Health District, Northern NSW Local Health District, St Vincent’s Hospital, Nepean Blue Mountains Local Health District, Central Coast Local Health District.

If your study is **Low or Negligible Risk (LNR)**, please complete the following sections of this checklist:

* Section 1
* Section 2
* Section 4
* Section 5

If your study is **Greater than Low Risk (GTLR)**, please complete all sections of this checklist:

* Section 1
* Section 2
* Section 3 – Only if your GTLR study is a **commercially sponsored clinical trial**
* Section 4
* Section 5

Below is a useful tool for researchers to use when submitting a Research Governance/STE application. The checklist can help ensure all necessary information and documentation have been provided for a governance submission in REGIS.

**Section 1: Please complete this section if your study is LNR, GTLR or a commercially sponsored clinical trial**

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| **Section 1: STE Application and Supporting Study Documentation** | | | | |
| **Item** | **Description** | **Yes** | **No** | **N/A** |
| **Site Specific Participant Information Sheet(s) and Consent Form(s) (PISCF) and any other documents that require site specific information such as local contact details** | This is a modified version of the Master Participant Information Sheet and Consent Form (and local PISCF if applicable) which includes information pertaining to the site at which the research is to be conducted, e.g. local contact details, local investigators and local logos on documentation.  Including version number and version dates.  If lead HREC is outside of NSW, Master documents need to be submitted. |  |  |  |
| **Payment** | Please check with the LHD/LHN’s Research Office regarding requirements for fee payment. |  |  |  |
| **ETHICS APPROVAL DETAILS** |  |  |  |  |
| **Item** | **Description** | **Yes** | **No** | **N/A** |
| **HREA** | Only required if approving HREC is outside NSW or if ethics approval pre-dates REGIS (prior to 2018). A copy of the ethics application form approved by the HREC. |  |  |  |
| **Ethics Approval Letter and any subsequent amendment approval letters** | Only required if approving HREC is outside NSW or if ethics approval pre-dates REGIS (prior to 2018). Original ethics approval letter and any subsequent amendment approval letters. |  |  |  |
| **HREC approved Master Participant Information Sheet(s) & Consent Form(s)** | Only required if approving HREC is outside NSW or if ethics approval pre-dates REGIS (prior to 2018). Documents should include version number and version dates. |  |  |  |
| **HREC approved study documentation as listed on HREC approval letter and any other subsequent amendment approval letters** | Only required if approving HREC is outside NSW or if ethics approval pre-dates REGIS (prior to 2018). |  |  |  |

**Section 2: Please complete this section if your study is LNR, GTLR or a commercially sponsored clinical trial**

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| **Section 2: Departmental Approvals, Funding & Budgets** | | |  |  |
| **Item** | **Description** | **Yes** | **No** | **N/A** |
| **Have you considered all supporting internal departments & nominated them in REGIS? E.g. medical imaging, pharmacy, medical records, other wards, depts etc. *If you do not nominate departments this may cause delays in being able to start your study*** | Example: If you’re employed in respiratory medicine, but you need to recruit patients from ICU, then you will need sign-off from the head of ICU. |  |  |  |
| **Pathology Testing** | Does your study engage the use of external pathology services, such as NSW Health Pathology, for a research project? |  |  |  |
| **If you are using external service providers for any study related activities, you need to provide a Service Agreement.**  ***Contact the LHD/SHN Research Office for templates*** | This Service Agreement is designed for the procurement of a service for a clinical trial or research study, without the Service Provider being a Site. It is designed for a Study only and not for on-going service provision. E.g. external radiography services such as PRP, ophthalmology services. |  |  |  |
| **Site Access and eMR Access for External Researchers** | If you have an external researcher working on this project, please check the LHD’s research office website where you will be conducting the research to organise relevant access (see links at the bottom of the checklist for more information). Please make sure you nominate all external researchers that are coming on site or that will be accessing identifiable patient data on your STE application. |  |  |  |

**Section 3: Please complete this section if your study is a commercially sponsored clinical trial. If your study is LNR or GTLR, and it is not a commercially sponsored clinical trial, you do not need to complete this section.**

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| **Section 3 : Additional requirements if your study is a commercially sponsored clinical trial** | | | | |
| **Item** | **Description** | **Yes** | **No** | **N/A** |
| **Clinical Trial Research Agreement (CTRA)** | As per [PD2010\_056](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2010_056.pdf) all clinical trials with an external sponsor must have a written agreement in place. Five CTRA templates have been approved for use in NSW Public health organisations (PHOs) and can be found [here.](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/)  Please note that any new clauses included at Schedule 4 or 7 must be approved by the South Eastern Border States ([SEBS Committee](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/)) and evidence of SEBS approval must be provided with the application. |  |  |  |
| **Medicines Australia Form of Indemnity** | For commercially sponsored clinical trials, the sponsor must provide an executed [Medicines Australia Form of Indemnity.](https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/) Please click [here](https://www.nslhd.health.nsw.gov.au/Research/ResearchOffice/Pages/Regulatory-Documents.aspx) for further information on indemnity forms. |  |  |  |
| **Certificate of Currency of Insurance** | For all **commercially sponsored clinical trials**, an Insurance Certificate must be submitted with the governance application. The insurance certificate should: Cover a minimum of $20 million (AUS); have an Australian-named sponsor; and an excess/deductible or self-insured retention amount not greater than $25,000 for each and every claim.  For more information, see NSW MoH Policy [Clinical Trials – Insurance and Indemnity PD2011\_006](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2011_006.pdf), section 2.2. |  |  |  |
| **If your study requires NSW Civil and Administrative Tribunal (NCAT) approval, please obtain this approval prior to submission. If you are unsure, please contact your LHD/LHN Research Office.** | Under *Part 5* of the *Guardianship Act 1987* (NSW), clinical trials which seek to involve a person aged 16 years or older with decision making disability must be approved by the Guardianship Division of the NSW Civil and Administrative Tribunal (NCAT). Further information: <https://ncat.nsw.gov.au/> |  |  |  |
| **Collaborative Group Clinical Trial Research Agreement** | Templates have been approved for use in NSW Public Health Organisations (PHOs) and can be found [here.](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) |  |  |  |

**Section 4: Please complete this section if your study is LNR or GTLR and it is an investigator initiated and/or collaborative trial**

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| **Section 4: Additional requirements if your study is an investigator initiated and/or collaborative trial** | | | | |
| **Item** | **Description** | **Yes** | **No** | **N/A** |
| **Research Collaboration Agreement** | 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 contact the local Research Office for further information on Research Collaboration Agreements for investigator-initiated or collaborative group research. |  |  |  |
| **Material Transfer Agreement (MTA)** | If your research involves a transfer of data, materials or samples (such as cell lines, blood, tissue, CT and MRI scans and other clinical data) to an external site and does not require a CTRA or other collaboration agreement a MTA may be required.  It is strongly recommended that you contact your LHD/SHN Research Office to ascertain this requirement. |  |  |  |
| **Certificate of Currency of Insurance** | For **non-commercial sponsors**, please see the requirements here: [PD2011\_006 Clinical Trials: Insurance and Indemnity](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2011_006.pdf).  **For non-commercially sponsored research, PHOs must ensure sponsors have indemnity or insurance arrangements that are sufficient to cover their sponsor-related liabilities. This insurance should cover a minimum amount of $10 million (AUD).**  **Research Offices collect and store on file certificate insurances from non-commercial sponsors, so that researchers are not repeatedly required to obtain and provide this. Occasionally when a certificate has expired you may be asked to obtain and provide evidence of insurance.** |  |  |  |
| **If your study requires NSW Civil and Administrative Tribunal (NCAT) approval, please obtain this approval prior to submission. If you are unsure, please contact your LHD/LHN Research Office.** | Under *Part 5* of the *Guardianship Act 1987* (NSW), clinical trials which seek to involve a person aged 16 years or older with decision making disability must be approved by the Guardianship Division of the NSW Civil and Administrative Tribunal (NCAT). Further information: <https://ncat.nsw.gov.au/> |  |  |  |

**Section 5: Please complete this section if your study is LNR, GTLR or a commercially sponsored clinical trial. Only complete the sections relevant to the local site where you are submitting your governance application.**

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| **LHD/LHN Specific Requirements** | | | | | | | |  |  |
|  | **CCLHD** | **NSLHD** | **NBMLHD** | **NNSWLHD** | **SCHN** | **SLHD** | **St Vincent’s** | **SWSLHD** | **WSLHD** |
| **Cover Letter** |  |  |  | N/A | N/A |  |  | N/A |  |

**For more detailed guidance about your site specific application at the site where you will be conducting research, please visit the following links:**

CCLHD: [Research - Central Coast Local Health District - NSW Health](https://www.cclhd.health.nsw.gov.au/research-and-learning/research/)

NSLHD: [How to submit for research governance? - Research Ethics and Governance - Northern Sydney Local Health District (nsw.gov.au)](https://www.nslhd.health.nsw.gov.au/Research/ResearchOffice/Pages/Research-Governance.aspx)

NBMLHD: [Research Governance - Nepean Blue Mountains Local Health District (nsw.gov.au)](https://www.nbmlhd.health.nsw.gov.au/researchoffice/research-governance)

NNSWLHD: [What is Research Governance? - Northern NSW Local Health District](https://nnswlhd.health.nsw.gov.au/human-research-ethics-and-governance/what-is-research-governance/)

SCHN (Westmead): [Research governance | Sydney Children's Hospitals Network (nsw.gov.au)](https://www.schn.health.nsw.gov.au/research/ethics-governance/ethics-governance/research-governance)

SLHD RPA: [SLHD RPA - Research Ethics and Governance Office - Governance (nsw.gov.au)](https://www.slhd.nsw.gov.au/RPA/Research/governance2.html)

SLHD Concord: [SLHD Concord Hospital - The Concord Research Office - Research Governance (nsw.gov.au)](https://www.slhd.nsw.gov.au/Concord/Ethics/ResearchGovernance.html)

St Vincent’s Hospital: [Submitting for Governance & Site Authorisation (SSA) - St Vincent's Hospital Sydney (svhs.org.au)](https://www.svhs.org.au/research-education/research-office/governance-and-site-authorisation)

SWSLHD: [SWSLHD - Research and Ethics Office - Site Specific Application (SSA) (nsw.gov.au)](https://www.swslhd.health.nsw.gov.au/ethics/site.html)

WSLHD: [Ethics & Governance - WSLHD (nsw.gov.au)](https://www.wslhd.health.nsw.gov.au/Education-Portal/Research/ethics-governance)