|  |  |  |
| --- | --- | --- |
| **General guidance for research governance (SSA) submissions** | | |
| * Prior to starting please review the [**pre-submission guide**](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/prior-to-starting)and [**Research Office website**](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home). This is a detailed reference for all aspects of research ethics and governance applications. * Additional support:   + - **Q&A drop-in sessions**, times and link on our [website](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home).     - Email [SESLHD-RSO@health.nsw.gov.au](mailto:SESLHD-RSO@health.nsw.gov.au). * Governance applications i.e.., Site-Specific Applications (SSA), must be completed and submitted within [**REGIS**](https://regis.health.nsw.gov.au/) (Research Ethics Governance Information System, operated by NSW Health)   + REGIS How-To guides and videos can be accessed [here](https://regis.health.nsw.gov.au/how-to/).   + For REGIS technical issues (i.e. cannot upload/submit/login) please contact the REGIS Help Desk on 1300 073 447. * An SSA/governance application (reference 2024/STEXXXXX) is required for each study site, in addition to ethics approval. | | |
| **Submission checklist – All Site-Specific Applications** | | |
| Document | Notes & guidance | Submitted |
| SSA form | * B1- The site name must be consistent with the site listed in the HREC approval letter. * B2-The site Principal Investigator (PI) must be consistent with the PI approved at ethics stage. * The PI must be a permanent SESLHD employee. * B8- Any non SESLHD-investigators coming on-site or accessing identifiable SESLHD systems/databases must obtain contingent worker status prior to commencing research activities. If applicable, please contact [SESLHD-ContingentWorkers@health.nsw.gov.au](mailto:SESLHD-ContingentWorkers@health.nsw.gov.au). This requirement does not apply to students in a placement and VMOs. * Part C-All relevant Heads of Department must be identified. Please note that the SSA will not be available to the Research Office until all HODs have indicated their support in REGIS. * Part E-Costs and funding must be consistent with the budget form and research agreement if applicable. * Part E- Please note that time taken away from the investigators’ usual duties (e.g. clinical time) to complete this research project constitutes in-kind costs. | Yes |
| Ethics-approved documents | * If the project has been approved by an external HREC, i.e. outside of NSW or ACT and not in REGIS, a copy of all ethics-approved documents and all HREC approval letters must be uploaded. | ☐Yes  ☐N/A |
| Site-specific documents | * A site-specific version of all participant-facing documents is required. * The site-specific document: * Is based on the current approved Master version. * Includes the NSW Government logo and the name ‘South Eastern Sydney Local Health District’ * Has a footer that includes the Master and site-specific version numbers and dates, e.g.:   *Master PICF v3 dated 01/02/2024.*  *Prince of Wales Hospital v1 dated 10/05/2024.*   * The local contact for complaints is South Eastern Sydney Local Health District Research Office/ Research Governance Officer |Ph: (02) 8797 7605 | E: [SESLHD-RSO@health.nsw.gov.au](mailto:SESLHD-RSO@health.nsw.gov.au)) | Yes  N/A |
| GCP certificate | * The site PI must provide a copy of their current Good Clinical Practice (GCP) certificate. For clinical trials, evidence for GCP training is required for all site investigators. | ☐Yes |
| Data Custodian Request Form | * When data that is held in a SESLHD data collection (unit record data) are being released outside of the LHD for research purposes, a [Data Custodian Request](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines) form is required. This applies to both identifiable and de-identified data. * The form should be signed by the Principal Investigator/s who will be responsible for releasing the data outside of the LHD. | Yes  N/A |
| **Additional documents required for Clinical Trials** | | |
| Method of Payment (MoP) Form | * Submission of completed [form](https://www.seslhd.health.nsw.gov.au/sites/default/files/groups/Research%20Website/Policy%20%26%20Guidelines/SESLHD-MoP-Fee%20Form-1-Nov-2023.docx) is mandatory for all clinical trials * The review of all clinical trials with an external non-commercial or commercial sponsor will incur a [fee](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/IB2023_026.pdf) according to [NSW health policy](https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_015). | Yes |
| Clinical Trial Management System (CTMS) registration | * Any clinical trial that meets all of [these criteria](https://www.medicalresearch.nsw.gov.au/clinical-trial-management-system/) must be entered into the NSW Health Statewide CTMS * A screenshot of the registration page that displays the REGIS STE code must be provided. * **Please also provide the CCID here:** | ☐Yes  ☐N/A |
| Clinical Trial Research Agreement (CTRA) or other agreement | * Please refer to Medicine Australia’s [website](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) to determine the appropriate template for your study. * SESLHD Legal Entity details:   Name: South Eastern Sydney Local Health District  Address: District Executive Unit, Level 4  The Sutherland Hospital & Community Health Service  Cnr The Kingsway and Kareena Road  CARINGBAH NSW 2229  ABN: 70 442 041 439   * Contact for notices: site PI. * The agreement must be partially executed, i.e. signed by the sponsor and the site PI. The ‘institution’ section must be left bank. * Special conditions (schedule 4 or 7) usually require [NaCTA approval](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) * [Current governance review fees](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/IB2023_026.pdf) must be included as costs and/or payments if covered by the sponsor. | ☐Yes |
| Form of Indemnity | * For commercially sponsored clinical trials only * Templates [here](https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/) | ☐Yes  ☐N/A |
| Certificate of Currency | * Mandatory for all clinical trials | ☐ Yes |
| Clinical Trial Notification (CTN) | * For clinical trials involving an 'unapproved' therapeutic good, please submit evidence of submission to the Therapeutic Goods Administration ([Clinical Trial Notification](https://www.tga.gov.au/clinical-trials)). The SSA’s site must be listed. | ☐Yes  ☐N/A |
| Budget | * A separate [budget spreadsheet](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines) is required * Costs and payments must be consistent with those listed in the SSA form and the agreement. * [Applicable review fees](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/IB2023_026.pdf) must be included in the budget as costs and/or payments if covered by the sponsor. | ☐ Yes |
| **Collaborative studies not involving clinical trials** | | |
|  | * A [Collaborative Research Agreement for projects not involving clinical trials](https://www.australianclinicaltrials.gov.au/resources/collaborative-research-agreement-template-projects-not-involving-clinical-trials) may be required. Word Template [here](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines). Please contact the Research Office for advice. | Yes  N/A |