|  |
| --- |
| **General guidance for research governance (SSA) submissions** |
| * PRIOR TO SUBMISSION - 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:
	+ - **Pre-submission meeting**

A pre-submission meeting confirms that your application is complete which will streamline the review and approval process. This is available for all studies, and strongly recommended for studies that are institution/investigator-initiated (e.g. SESLHD sponsored) or have an external (e.g. non-SESLHD) non-commercial sponsor (e.g. tertiary institution). Meetings are via Teams. Please book a meeting using [this booking page](https://outlook.office.com/book/RSOBookingsSESLHD%40bookings.health.nsw.gov.au/s/JWDC3pP5hkKnTOZ3vqck5Q2?ismsaljsauthenabled).* + - **Q&A drop-in sessions on Teams**, 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.
* 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. This requirement does not apply to students in a placement and VMOs.
* Part C-All relevant Heads of Department (HOD) 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. It is the applicant’s responsibility to follow-up timely approval from HOD/s.
* 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 non-financial costs and are to be estimated in dollars in the SSA
 | [ ] 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  |
| 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)
 | [ ] Yes[ ] N/A |
| GCP certificate and CV  | * The site PI must provide a copy of their current Good Clinical Practice (GCP) certificate and CV.
 | [ ] Yes |
| Data Custodian Request Form  | * When research-generated or medical record 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 |
| Budget  | * Financial and non-financial costs (e.g., in-kind contribution of staff time to research tasks during usual clinical duties) must be stated in SSA. Non-financial (in-kind) costs can be estimated using published award hourly rates.
* State amount of funding provided (if any) and the source. A budget template is available if the budget cannot be adequately described in the SSA or cover letter.
* State if there is an overall **cost-surplus (and what will the surplus be used for)**, **cost-deficit** (who will be paying for the deficit) or it is **cost-neutral**.
 | [ ] Yes |
| **Additional documents required for Clinical Trials** |
| GCP certificate and CV | * Current Good Clinical Practice (GCP) certificate and CV is required for ALL site investigators/team members
 | [ ] Yes |
| 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).
* Please note that there are **new research fees for clinical trials** set by OHMR (Ministry of Health) that will be payable from the 1st July 2025 - PD2025\_017
 | [ ] Yes |
| Clinical Trial Management System (CTMS) registration and Site Engagement | * Any clinical trial that meets all of [these criteria](https://www.medicalresearch.nsw.gov.au/clinical-trial-management-system/) = is mandatory to be entered into the NSW Health Statewide CTMS as directed by the NSW Ministry of Health.
* A screenshot of the registration page that displays the REGIS STE and CCID code must be provided.
* **Creating** a site Engagement is mandatory and an extra step in addition to CTMS registration where a CCID number is generated. Site Engagement can be created by accessing the ‘Site Engagements’ tab in the CTMS side bar menu (see p52 of the CTMS Training Manual).
 | [ ] Yes CCID Code: Created a site engagement?[ ] Yes  |
| 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.
* Please see the CTRA guide on the SESLHD website: [website](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home)
* SESLHD Legal Entity details:

Name: South Eastern Sydney Local Health DistrictAddress: District Executive Unit, Level 4The Sutherland Hospital & Community Health ServiceCnr The Kingsway and Kareena RoadCARINGBAH NSW 2229ABN: 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 for the SESLHD Director of Research – Professor Georgina Hold to sign last.**
* Special conditions (schedule 4 or 7) usually require [NaCTA approval](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/)
* **In Schedule 2:** Please ensure that all costs for research office review are referred as **“in accordance to current Ministry of Health Research Fee Policy”**
* [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/)
* Required to have at least 6 months validity
 | [ ] Yes |
| Certificate of Currency  | * Mandatory for all clinical trials
* Has at least 6 months validity
 | [ ] 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.
* The **Approving Authority is SESLHD**
* The Approving Authority Contact Position is **SESLHD Research Operations and Governance Manager**
* The Approving Authority **Contact Phone is (02) 8797 7605**
* The Approving Authority Contact Email is **SESLHD-RSO@health.nsw.gov.au**
 | [ ] Yes |
| 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.
* State if there is an overall **cost-surplus (and what will the surplus be used for)**, **cost-deficit** (who will be paying for the deficit) or it is **cost-neutral**.
* Non-financial costs such as in-kind hours from staff on study tasks during usual clinical duties are also included within budgets. These can be estimated using published hourly rates.
 | [x] ~~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 |
|  | PRINCIPAL INVESTIGATOR DECLARATION  |  |
| **As Principal Investigator I declare to:*** Have reviewed the submission to be complete and in accordance to the SESLHD pre-submission guide
* Acknowledge that if there is no response for a request for more information after **30 days**, the study will be withdrawn to preserve the metric key performance indicator set by Ministry of Health.
* Understand that as the PI, in accordance to ICH-GCP, I am responsible for the entire conduct of the study at this site.
* That as PI I keep a log of any changes to study team members. That any future changes to study team members that are not the Coordinating Principal Investigator or Principal Investigator will not require an amendment.
* Any future team members the PI would like to add who are not SESLHD staff, may need to apply for contingent worker status (CWS) which is the responsibility of the PI (see pre-submission guide - <https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/governance>)
* Ensure requests for more information from the Research Office are responded to in a timely way. The Chief Executive of SESLHD has signed an agreement with the NSW Office of Health and Medical Research that Governance applications are processed within 60 days. Complete submissions and timely responses to requests for more information are crucial to meeting this published SESLHD metric
 |
| **Principal investigator’s name:**  |
| **Date: Signature:**  |