SESLHD Research Pre-Submission Guide

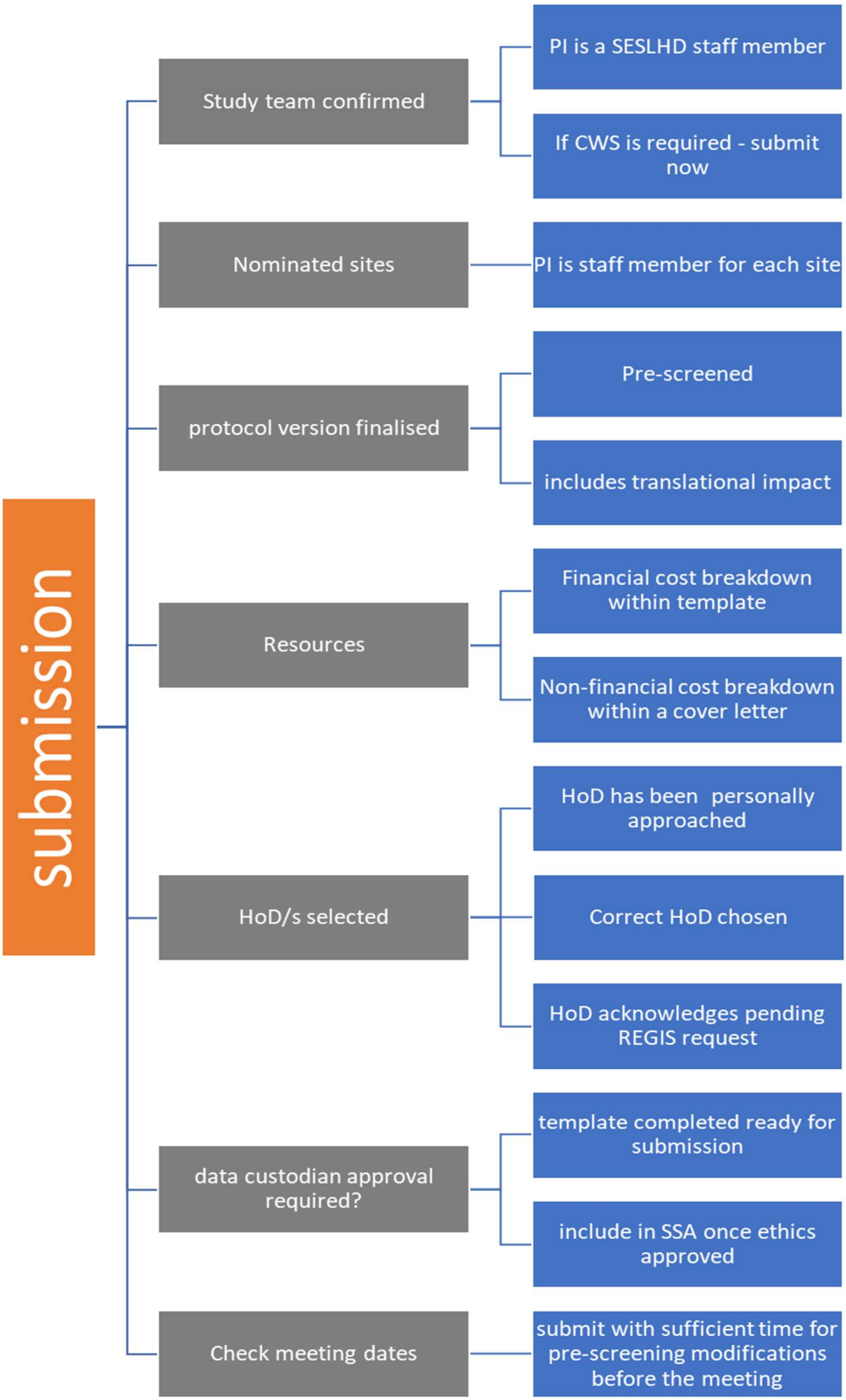


Figure 1 Pre-submission Map

*Please note that this guide will be regularly updated - check for the latest version on the SESLHD Research Website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/governance

Purpose and scope:

This is a guide to help researchers plan their studies in advance by providing a general overview of key elements that are essential in preparation **before submission to the REGIS platform for ethics or governance review.**

Clearly outline what impact do you expect to achieve from this study?

This will be a pivotal point when engaging with heads of departments whom you are requesting resources from and cost / benefit evaluation whether financial or in-kind costs. According to the Australian Research Council (ARC), the definition of research impact is "the contribution that research makes to the economy, society, environment or culture, beyond the contribution to academic research", (https://www.arc.gov.au/about-arc/strategies/research-impact-principles-and-framework).

Please ensure that you demonstrate the preparation and integration of research impact and implementation within your submission to leverage resources against the contribution/beneficence to the local health district and/or hospital site hosting your study.

Simultaneous requests or pre-planning within the timeline for efficiency.

Mapping what is required for your study - considering the time and avenues required for each element so they are aligned and if possible simultaneous, will allow for the most efficient timeline. **If you invest in robust consultation and pre-submission planning, it may save you a considerable amount of time**. Some aspects such as governance cannot be authorised until the ethics has been approved **BUT there are things you can prepare in advance *whilst* your ethics is under review, such as seeking contingency worker status for non SESLHD staff coming on site.**

Calculating Meeting dates and submission cut offs

If you seek information on the SESLHD research website within the early planning phase of your project BEFORE submitting into REGIS, you can find pivotal information towards preparing your expected timelines and documentation such as the meeting dates and submission cut off dates. **Please submit your application BEFORE the submission cut-off date with sufficient time for "eligibility" review**. If there is insufficient time for modifications before the meeting cut off = the application will not be eligible for review at the next meeting.

Your study sites

Plan carefully your sites and engage with principal investigators (PIs) within those sites in advance. Ensure they understand the responsibility the PI role holds? The PI must be a SESLHD staff member and in accordance to GCP certification - will be responsible for the conduct of the study on their nominated site.

Please see more on governance review of site-specific applications on page 12 or **https://www.medicalresearch.nsw.gov.au/app/uploads/2018/04/ACTJWG-resp-investigator.pdf**

Please ensure that the study's activity will be on a SESLHD site and not an external entity's site that is geographically within a SESLHD hospital or campus. For example: a study conducted within a laboratory managed by an external entity with external staff members, but the lab is within a SESLHD hospital = not a SESLHD site and requires governance authorisation from the appropriate entity and not SESLHD. Sites within the SESLHD jurisdiction can be found on this website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/governance

Study team roles and responsibilities

Components to consider in early planning stages are;

- Listing the relevant team members on the application and ensuring that these details correspond in both ethics and governance applications and all relevant documentation. Inconsistencies cause the return of applications for modification and verification which causes delays and unnecessary use of district resources.

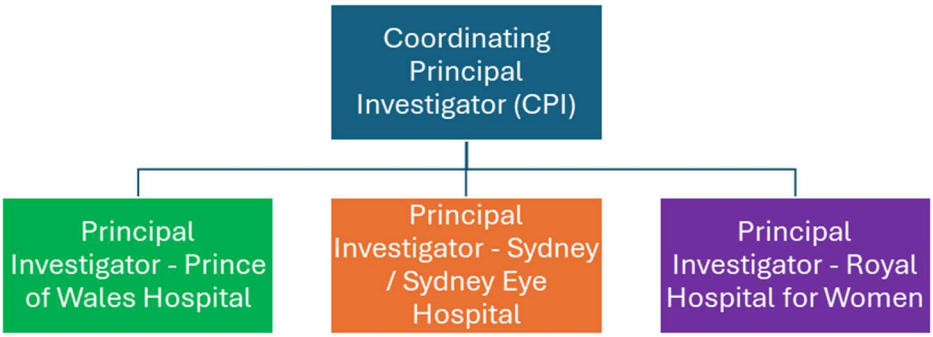
-Will members of your study team require contingency worker status? Are the non SESLHD staff members coming on site or accessing our data remotely? If necessary, contact SESLHD People and Culture – position maintenance: (seslhd-positionmaintenance@health.nsw.gov.au) to ascertain timeframes for applying for contingency worker status.

-Have you ensured the Principal Investigator is a permanent SESLHD Staff member or visiting medical officer?

-Has the PI completed GCP training?

-Are team members sufficiently trained/qualified for their roles within the study?

What is the difference between a Coordinating principal investigator (CPI) and principal investigator (PI)?



COORDINATING PRINCIPAL INVESTIGATOR (CPI) - is the individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators (PI's). For single site studies, the CPI and PI have the option to be the same person though must be a SESLHD staff member.

ICH GCP requires the Principal Investigator (PI) and other staff involved in a clinical trial to be qualified by education, training, and experience to perform their role and Good Clinical Practice (GCP) auditors/inspectors look for evidence that staff have received training commensurate with their roles and responsibilities.

The PI is the person responsible, either individually or as a leader of the researchers at a site, for the conduct of research at that site and should be able to demonstrate they can assume the PI role. The PI and all staff with significant trial related duties must maintain records of training (including an appropriate level of accredited GCP training) and qualifications. Staff must have appropriate and documented trial-specific training before performing any clinical trial activities.

Please note: The PI must be a SESLHD staff member and/or delegate staff must be qualified to perform their role including ICH-GCP training and REGIS competency to manage the project through the NSW Health state-wide platform REGIS. It is essential to have contact details (mobile phone) to the PI or delegate.

Definitions of roles and responsibilities concerning Coordinating principal investigator and Principal investigator for non-clinical trial studies can be found at: https://www.medicalresearch.nsw.gov.au/app/uploads/2018/04/ACTJWG-resp-investigator.pdf

IMPORTANT: It is the responsibility of the CPI/PI to ensure access rights have been given in REGIS (editing, contact person etc) to relevant team members. NAMELY, if the CPI/PI is taking leave or given notice to leaving the organisation = please ensure a delegate has been nominated. Please ensure this is done before submitting your application.

Please see resources available from the REGIS website: https://regis.health.nsw.gov.au/how-to

CPI/delegation functionality walkthrough video:

https://youtu.be/9yGH0UctRwc

Sharing access to an application or project – instructional video:

https://youtu.be/9yGH0UctRwc

Please Note: Ensure that there is an **institutional email address** provided within your REGIS account and studies created within REGIS. This will be reviewed at both eligibility to the ethics meeting as well as within committee review.

What if a study team member is not a SESLHD staff member?

A non-SESLHD staff member on the study team may require Contingency Worker Status. Please see the diagram:

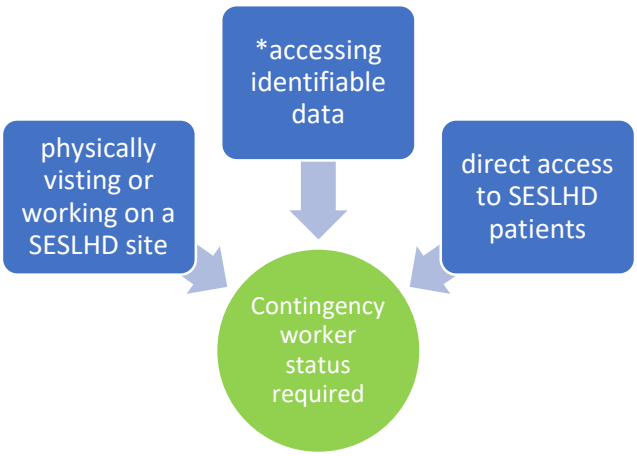


Figure 2- Contingency Worker Status Map

IMPORTANT: for non SESLHD staff members to access SESLHD data – the PI must submit a cover letter to the HREC Chair (if their ethics application is to SESLHD HREC) stating the details of how the data will be de-identified before access is granted to the non SESLHD staff member. For Site Specific Applications where the lead HREC is external to SESLHD, please submit a cover letter with the same detail within your Site-Specific application. Please see on the SESLHD Research website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/data for exporting data from SESLHD.

If the non SESLHD study team member will require Contingency Worker Status – please contact SESLHD People and Culture:

Please send any enquiries/documentation regarding the setting up of contingent workers and/or positions to: SESLHD-ContingentWorkers@health.nsw.gov.au

Please note the separation of contingent workers remains with the Local Roster Administrator team and enquiries re separations can be sent to: SESLHD-LocalRosterAdministrator@health.nsw.gov.au

What is Contingency worker status? How do I apply?

For Non-SESLHD staff who wish to conduct research on a SESLHD site or access SESLHD data – they may require to apply for contingent worker status through the study's principal investigator:

A Contingent Worker is an employee of NSW Health who is not paid through the NSW Health payroll and will be maintained in StaffLink.

Contingent Workers may include:

- Students, Volunteers, Contractors, Chaplains
- Health Executive Service (HES)
- Honorary Medical Officers (HMOs), Clinical Observers
- Visiting Medical Officers (VMOs), Visiting Dental Officers (VDOs)
- Agency Staff
- Defence Employees

Maintaining Contingent Worker information in StaffLink will accommodate global reporting; provide access to Manager Self Service (MSS) and/or Employee Self Service (ESS) or access to NSW Health systems (SWIS) where required; and record appropriate service and work-related employment screening checks which can be qualified against the position requirement and person record.

Contingent Workers (CW) should be assigned to specific positions that reflect the real organisation (cost centre) and the Manager that the position reports to (Parent Position).

For information on how to apply, the Principal Investigator will need to go on to the intranet:
seslhdweb.seslhd.health.nsw.gov.au/People_and_Culture/Contingent_Workers_Portal

If you are submitting a study as a student

The Protocol and Participant Information Sheet should clearly state the student name/s, their supervisor/s and the degree being undertaken, e.g., *'<NAME>* is conducting the study as part of the requirements for *<NAME OF DEGREE>*, under the supervision of *<NAME(s)>.*'
The Protocol should also specify the aspects of the research that the students will conduct for a degree. A publication/dissemination plan should also be provided in the Protocol.

Please note: it is strongly recommended that: 1) you nominate yourself as the Coordinating Principal Investigator (CPI) of the overall study and the supervisor as the Principal Investigator (PI) for the SESLHD site. As the PI needs to be a SESLHD staff member. 2) your submission is pre-reviewed by your supervisor or another third party BEFORE submitting your application within REGIS.

Will you need data custodian approval?

Are you exporting data (either unidentifiable, coded or identified) from SESLHD to an external entity? Please see the section data on the SESLHD Research website https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/data and template and guide can be found under: "forms and templates" https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines.

Nominating your heads of department

Engage with your key stakeholders individually and personally in the initial stages of your planning phase, namely your head of departments for resource requests. If you do not have approval for a resource request- this will evidently jeopardise the future, feasibility or detrimentally delay the project. The application will not be reviewed within the research office without all relevant HoD/s approvals.

The head of Department is not in REGIS for me to choose from the menu:

Please ensure that you have the correct Head of dept.(or HoD) – if the intended HoD is not available in REGIS to choose from – please send an email to SESLHD-RSO@health.nsw.gov.au where the research office will send a request to be sent to the Ministry of Health REGIS team for the addition to be made. **PLEASE DO THIS BEFORE SUBMITTING YOUR SSA INTO REGIS.** So that we can plan this in advance of your submission. ***If you are adding a Head of Dept that does not exist in REGIS, they will need to create a REGIS account. Please refer to the REGIS website:*** https://regis.health.nsw.gov.au/Register

Head of Dept. (HoD) approval

Conflict of interest: If the head of a department is a study team member, then that person **cannot** sign the head of department approval (essentially the resource request) for their own study, this would be considered a conflict of interest. Their next line manager's approval will need to be sought for head of department sign off.

- **All Principal Investigators will require their next line manager to be included in the list of HoDs to approve their study.**
- **Your application will not progress to the Research Office for review until all HoDs have approved your request through REGIS.**

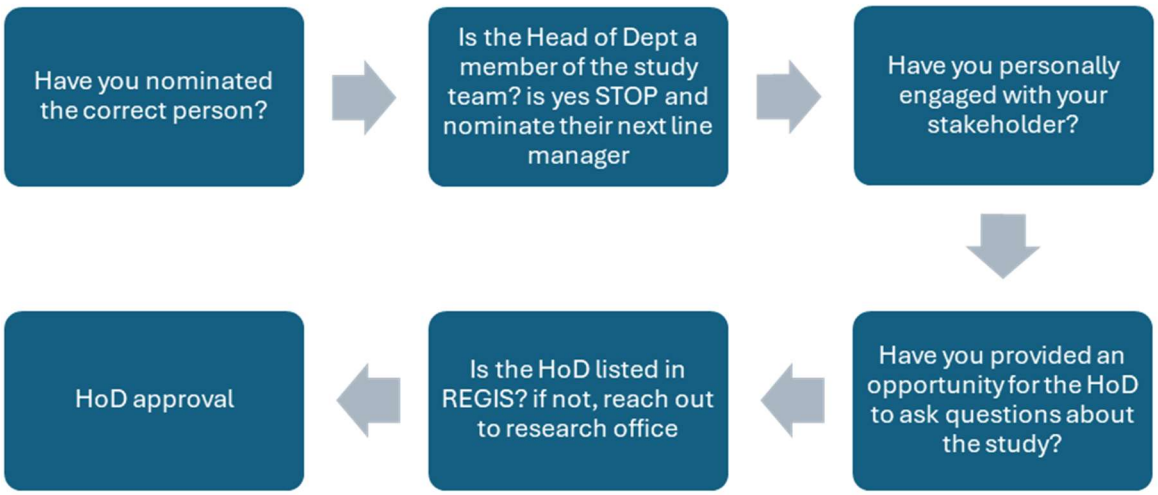
Within the application process, the research office will not see or receive your application (it will not appear on our screens to be processed and cannot be processed) until the head of department/s have approved your request through REGIS.

It is strongly recommended and essential that you personally approach the head of dept/s to:

- Avoid delays to your project timeline for your approval through REGIS.

- Provide a cover letter stating the resource request from that particular head of department (**including financial and/or non- financial costs**). For example; to the line manager of the PI for the number of hours in kind.
- Inform the HoD that they will receive an email generated through REGIS requesting approval for your project's resource requirements. If they do not have a REGIS account, please see: https://regis.health.nsw.gov.au/Register
- Provide the opportunity for the Head of Department to pose questions to the PI or delegate.
- Ensure that you have the correct Head of Department. If the HoD within REGIS is incorrect. Please provide the following details:
  the Regis reference No. year/STEXXXXX,
  the name of the HoD to be removed from REGIS with their exact role title
  the name of the HoD to be added and their exact role title
  within an email to SESLHD-RSO@health.nsw.gov.au

If you are adding a Head of Dept that does not exist in REGIS, they will need to create a REGIS account. Please refer to the REGIS website:
https://regis.health.nsw.gov.au/Register



Pre-review

It is strongly recommended to seek peer review or project appraisal from someone within the relevant field/expertise or discipline BEFORE submitting into REGIS for ethics review. Submissions that have not been pre-reviewed could risk delays due to necessary or major modifications found during committee review requiring return to the next meeting. The research office cannot advise on aspects such as study design.

Mandatory templates to be pre-filled in preparation for submission

Templates and checklists for payments, ethics and governance submissions are available on the research website which are mandatory as they will facilitate your review and facilitate eligibility requirements.

Where can I find fundamental information regarding ethics and governance applications?

Websites:

SESLHD Research:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home

NHMRC- National Statement:

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023

The NSW Office of Medical Health and Research

https://www.medicalresearch.nsw.gov.au/ethics-governance-draft/

The difference between ethics and governance?

Figure 3 - Ethics & Governance Map

Ethics applications

Ethics applications are submitted and reviewed separately to governance applications. Please note: An ethics approval must be obtained before a governance authorisation can be granted.

Ethics review pertains to all research involving humans conducted within the NSW public health system which must be ethically and scientifically reviewed and approved by a Human Research Ethics Committee (HREC) in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007).

Please note: Ethics applications are **approved** and SSA applications are **authorised.**

Governance applications

Please note: Studies cannot commence within SESLHD without SSA authorisation. If your SSA has been granted **authorisation with condition** – the condition must be fulfilled (an amendment submitted) before full authorisation can be granted and the study commence at that site.

For further information on site authorisation please visit: https://www.medicalresearch.nsw.gov.au/site-authorisation

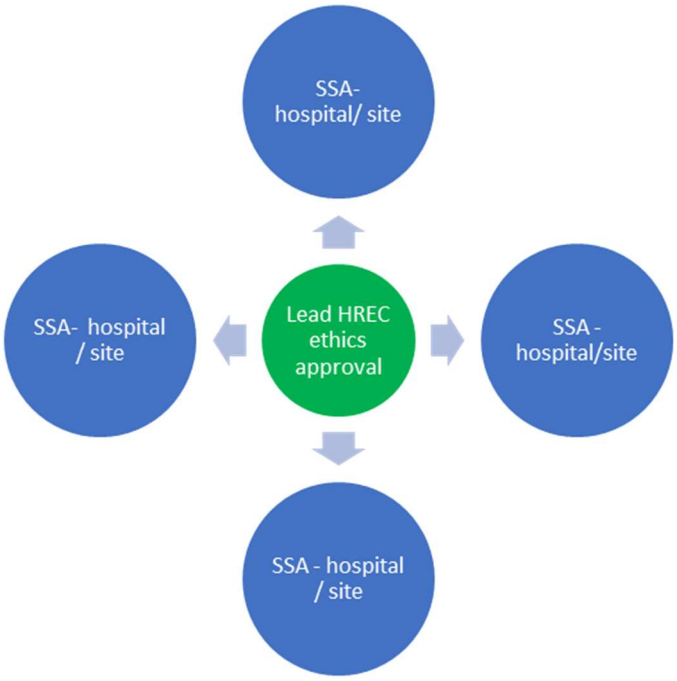


Figure 4 - HREC approval to sites

In addition to ethical and scientific review, all human research that takes place in NSW public health organisations, or that requires support from a NSW public health organisation in the form of access to participants, tissue or data, must be reviewed and authorised by the organisation's Chief Executive, or their delegate before commencement. **Projects must not commence until the applicant has received governance authorisation.**

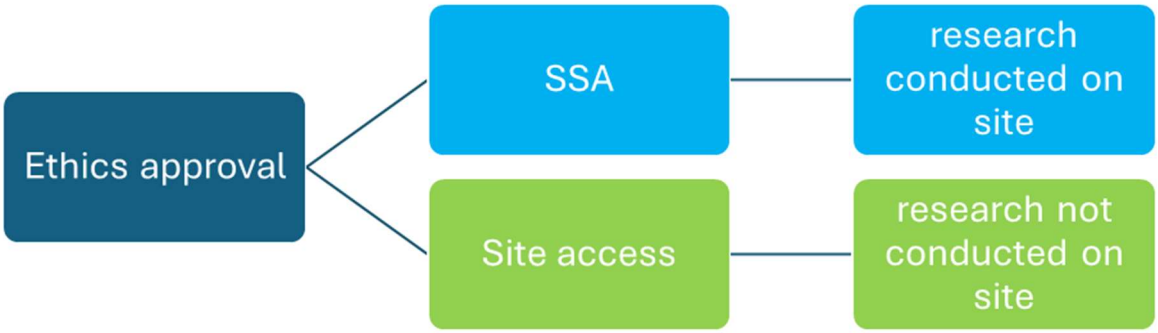
If you receive a notification that your study has been **Authorisation with condition,** this will require submission of the missing condition either via email or governance amendment in order to commence the study.

NOTE: Ethics = approves all sites that the study will be conducted on regardless of whether internal or external to SESLHD

Governance = The SESLHD Research Office provide local site-specific authorisation and can only be given to sites that are within SESLHD

What differentiates a site access and Site-Specific Application (SSA)?

Research projects that require access to SESLHD staff but do not involve the physical conduct of research at SESLHD sites, can apply for authorisation of a site access as opposed to Site Specific Authorisation (SSA).



Site access

Requests for access request review should be made by the Coordinating Principal Investigator to the Research Governance Officer via email (SESLHD-RSO@health.nsw.gov.au). The Coordinating Principal Investigator is also responsible for obtaining written agreement from relevant heads of the facilities, locations and services that will provide the access required. Site access requests for access to data, physical visits to sites, direct contact with patients and staff will generally be advised to submit a site-specific application and nominate a SESLHD staff member as the principal investigator (PI).

To submit a site access for SESLHD please first check the criteria on the website (https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/governance/site-access) for **the requirements** to submit to the research office via an email to SESLHD-RSO@health.nsw.gov.au:

- A completed site access form from https://www.medicalresearch.nsw.gov.au/Site-authorisation/
- Written support from the relevant head/s of department/s (email accepted)
- A cover letter. In the request the application should provide the following information , at a minimum
  - Project title and short title
  - Relevant project identifiers
  - Coordinating Principal Investigator name and contact information
  - Name of the study sponsor, if applicable
  - Human Research Ethics Committee approval letter with SESLHD site/s listed
  - The resources/services being requested
  - The proposed process for accessing those resources/services
  - Attached letters or emails confirming the support of each facility head of department,location or service(written evidence of support - emails accepted if all listed elements above mentioned are addressed)
  - If distributing a survey or conducting an interview, please include a data dictionary or list of questions that will be posed.

Site Specific Applications (SSA) / Governance applications must be submitted and processed through REGIS.

What is REGIS?

REGIS is the Ministry of Health led state-wide platform in which all ethics and governance applications are submitted, reviewed and approved through. All post approval reviews and processing within SESLHD are conducted through the REGIS platform.

Please note: Researchers are strongly advised to gain competency with REGIS to not only submit their applications but for the overall management of their studies throughout the duration of their HREC approval. This will facilitate CPI/PI ongoing responsibilities such as submitting safety reporting, mandatory annual reports, amendments, document management and archiving. Training is recommended.

The REGIS team at the NSW Office of Health and Medical Research offer:

- How to guides
- Training videos
- Online Training sessions facilitated by subject matter experts

Please visit the website for more details: https://regis.health.nsw.gov.au/ or https://regis.health.nsw.gov.au/content-resources/

My health learning course:

For IT technical and access issues please contact:

If you would like to provide feedback on the REGIS platform, please visit: https://regis.health.nsw.gov.au/your-feedback/your-feedback/

Please ensure you have read the initial paragraph within this guide on what to do BEFORE submitting your application so that you have **all the necessary documentation and resources before submitting into REGIS**. This will streamline the process and avoid unnecessary delays within your timeline.

Please see below the reference to the codes that will relate to each study. Each time you refer to your study's ethics or governance application or project – you will need to provide the REGIS code for reference.

The **PID code** will be generated once you register your project. **The ETH** code will represent your ethics application. There will only be one ethics application regardless of how many sites the study will be conducted on. However, each **STE code** will represent an individual site, hence you may have multiple sites and multiple different

STE numbers. However, those STE numbers will relate back to a “parent” registration (PID number) or “parent” ethics application (ETH number). Please see diagram below:

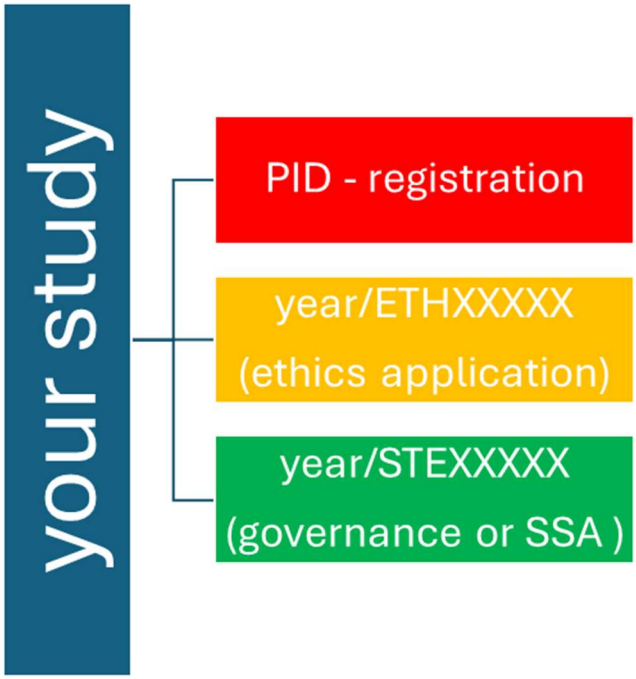
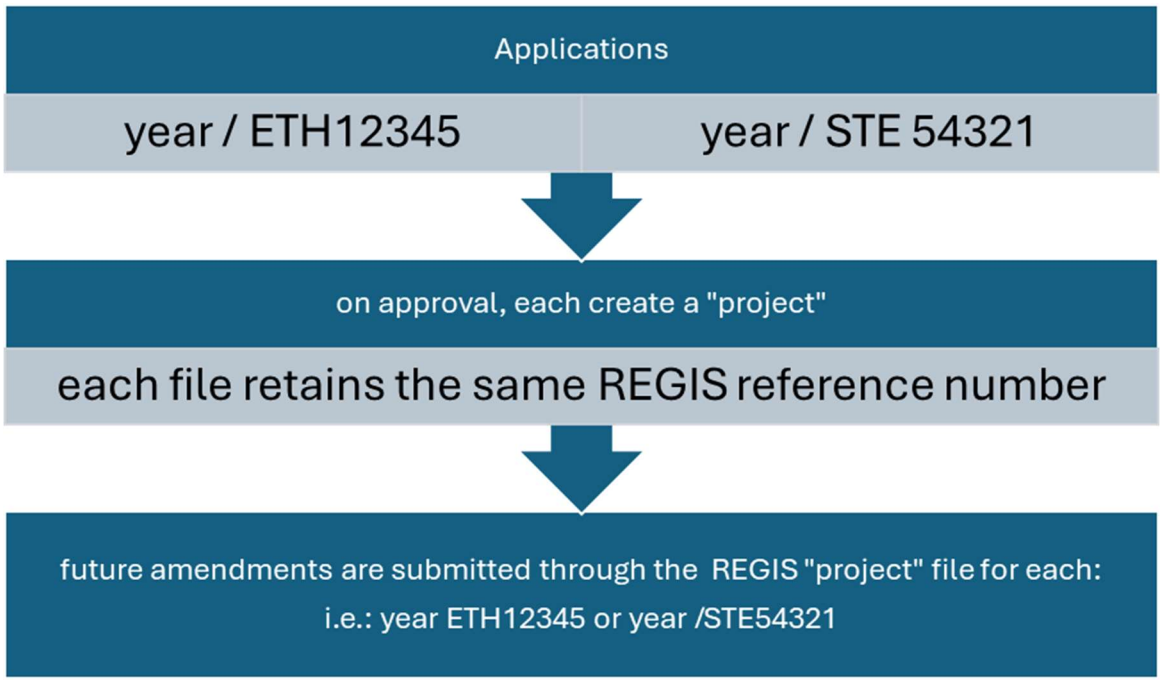


Figure 5 - REGIS application map

If the study is approved and conducted over multiple sites – each site may have its own SSA application and REGIS reference number. You can apply for a district wide study under the single SSA application if it is being conducted across the district.

Once your study has ethics and/or governance approval – the REGIS account for each will create a “project” from the application with the same reference number.



What is NMA?

National Mutual Acceptance (NMA) is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. The Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria and Western Australia participate in NMA. Single ethical and scientific review for a multi-centre human research project can be provided across seven of the participating states/territories.

Please note: not all HRECs are NMA certified. Please see website for more details for NMA listed HREC Committees that you can apply to: https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance

UNSW HREC ethics approvals will not be accepted for SESLHD governance applications.

How long does ethics and governance applications take to process?

Please note: To ensure eligibility to the nearest ethics committee meeting, it is recommended to submit your application with **sufficient time for the research officer to screen and request more information before the submission cut-off date**. If your application is submitted before cut-off but with insufficient time for pre-screening review for meeting eligibility– it may risk being "ineligible" for review at the next

meeting. It is important to ensure that the applications are of a standard that will facilitate review. If you submit with sufficient time for screening and modifications – the application will be of better standing for approval at the meeting. Hence, less likely to affect your timeline. In accordance with the National Statement:

> 5.3.5 Research proposals should be clear and comprehensive, and written in language that is easily understood by ethics review bodies. Researchers should be aware that the submission of poor quality proposals for review may delay the review, ethical approval and/or institutional authorisation process, with consequent impact on potential participants in the research or the community.

The ethics meeting minutes are drafted by the research officers and finalised by the Committee Chair approximately within 6 working days in total, subsequent to the meeting.

The following documents are mandatory, to be submitted within your application, completed and concise:

- Researcher checklists for both ethics and SSA (each submission)
- Method of payment form (MoP) for both ethics and governance within SESLHD
- Data Custodian request template (for any data leaving SESLHD)

The Chief Executive of SESLHD has signed an agreement with the NSW Office of Health and Medical Research to ensure that applications are processed within given metric timelines which include weekends and public holidays:

From submission to authorisation: Governance = 60 calendar days

From submission to approval: **Ethics** = 90 calendar days.

Hence, any submissions that are requested for more information or modifications that do not resubmit within 30 calendar days = the study will be withdrawn, and a new application will be required.

If you are planning leave or an absence during the period of the ethics and governance submission – it is the principal investigator's responsibility to ensure they have appointed a delegate with appropriate access to the necessary REGIS account and documentation for the process to continue during your absence and to avoid application withdrawal or delay.

Please note: If these documents are absent, incorrect or incomplete, your submission will be returned unreviewed and prolonging the timeline towards being eligible for the next meeting. Please plan for a realistic timeframe that allows for sufficient planning and preparation to avoid a submission that is ineligible and requires extensive modifications before the submission cut-off date.

For MoP and checklist templates please visit:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home

Ethics:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics

Governance:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/governance

Data custodian requests:

Information:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/data

Templates:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines

Ethics review

SESLHD Human Research Ethics Committee (HREC) Meetings are held monthly. Low Negligible Risk Committee Meetings are held fortnightly.

For Ethics process timeline – please refer to the SESLHD Research website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/ethics-application-process

For Ethics meeting submission cut off dates:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/committee-details-meeting-dates

However, your study may require additional or specific HREC approval:

Research involving:

- Persons in custody in NSW or staff of NSW Justice Health & Forensic Mental Health Network must be reviewed by the NSW Justice HREC. For more information: https://www.justicehealth.nsw.gov.au/research/jh-fmhn-human-research-ethics-committee

- Specifically, the health and wellbeing of Aboriginal people and communities, this must be approved by the Aboriginal Health & Medical Research Council Ethics Committee. Please note that this will require additional review from a NMA certified HREC to obtain SSA authorisation to conduct a study within SESLHD. For more information: https://www.ahmrc.org.au/resource/ethics-application-support-letter-form

- Clinical trials requiring access (including linkage) to state-wide data collections owned or managed by NSW Health or Cancer Institute NSW must be reviewed by the NSW Population & Health Services Research Ethics Committee. For

more information: https://www.cancer.nsw.gov.au/research-and-data/nsw-population-health-services-research-ethics-com

- 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/ For more information on ethical considerations specific to participants: Section 4 of the National Statement: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023

Protocol Templates can be found on youtube or the REGIS website:

Ethics amendments: https://youtu.be/ZN9Dh1mnSFk?si=reTOZBpQug54_N5L

SSA amendments: https://youtu.be/pEcfZY-jNhc?si=pneQJmhEtwcrmOiA

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines

Please note: Any HREC or subcommittee approval of a study and its related documents (noting the version reference) along with the sites of which the study will be conducted at, need to be clearly stated on the approval correspondence. Any changes to documents such as the protocol or master versions of the patient information/consent forms will require an amendment to be submitted through REGIS to the approving HREC committee. Information on submitting amendments can be found on the REGIS website:

Research risk pathways (ethics)

Quality Assurance /Quality Improvement activity does not receive HREC or sub-committee approval as it is not research. However, you may require HREC or subcommittee review in order to publish. Please check with the journal you wish to publish with. Please see the website for the QA form, (https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/ethics-application-process), and case report forms.

Research applications through SESLHD will be decided on the following two risk pathways that will determine what meeting it will be reviewed at:

Low/negligible risk = (LNR) HREC sub-committee Meeting)

Greater than low risk = (GTLR) HREC Meeting

For further guidance on what your study's risk category may be:

OHMR Policies and Guidelines: https://www.medicalresearch.nsw.gov.au/policies-guidelines/

NHMRC national statement:

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023

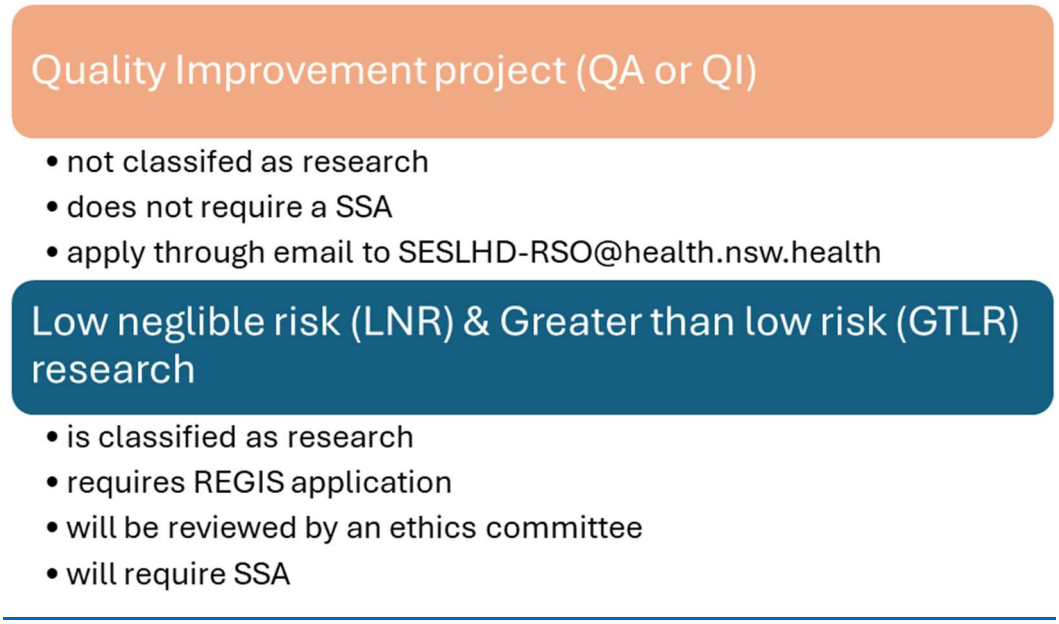
NMA list of HRECs (please note: UNSW HREC cannot approve studies to be conducted within SESLHD) https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research#download

Quality Improvement projects:

Please refer to the NSW Health – Office of Health and Medical Research website for more information on the determinant factors of a quality improvement or quality assurance submissions: https://www.medicalresearch.nsw.gov.au/quality-assurance-initiatives/

To submit a Quality Assurance or Quality Improvement project in SESLHD – please see the SESLHD Research website "does my project require ethical review?":

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/ethics-application-process



Clinical Trials

For all clinical trials, refer to the SESLHD Research Website for information on clinical trials including clinical trial management system requirements for governance submission review.

Link: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/clinical-trials

NOTE: All study team members within clinical trials will require to provide ICH-GCP certification within the SSA application – ensure that this is completed BEFORE governance application to avoid delays. Please see the SESLHD research website for information:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/education-q-a-sessions-working-groups

What is CTMS?

Clinical Trial Management System (CTMS) is software which enables oversight and management of clinical trials. The NSW Health CTMS is located within a secure website accessible to staff via single sign on.

Clinical trials are mandated to be uploaded into the CTMS platform. This will be reviewed on governance review. **Ensure that this is completed BEFORE SSA submission to avoid delays.** Governance authorisation cannot be provided if the CTMS minimum data set is not provided within the platform.

CTMS compliance rate is reported directly to Ministry of Health and SESLHD receives quarterly compliance reports by the NSW Office of Health and Medical Research.

The Principal Investigator (SESLHD staff member) can enter the sharepoint for NSW Statewide Clinical Trial Management System: https://nswhealth.sharepoint.com/sites/NSWH-CTMS/SitePages/Minimum-data-set.aspx

Please see the below criteria to ascertain whether your clinical trial will require entering into the CTMS system:

Which clinical trials are required to be entered into the CTMS?

Clinical trials required to be entered into the NSW Health Statewide CTMS must meet all of the following criteria

1. Meets the World Health Organisation (WHO) definition of a clinical trial which involves *prospectively assigning human participants or groups to health-related interventions to evaluate the effects on health outcomes* (WHO, 2020).
2. The clinical trial is conducted at NSW Health public facility or service, by a NSW Health employee or contingent worker, requiring a SSA within that district.
3. SSA authorisation is received on, or after, September 1st, 2023.
4. The clinical trial captures individual patient data.

Please ensure that evidence of the minimum data set is provided within your governance application. Please see the guide and resources on the CTMS website:

https://nswhealth.sharepoint.com/sites/NSWH-CTMS/SitePages/Minimum-data-set.aspx

Governance authorisation will not be provided without minimum data set being entered into the system.

Governance review

Governance review is conducted within the LHD's research office by research officers and does not require a committee meeting. Timelines and other important information can be found on the Research website:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/governance/site-specific-authorisation

Please note: 1) A Principal Investigator must be a SESLHD staff member and must be nominated for each SESLHD site. 2) Each site will require its own SSA or governance application 3) There are a few services that are physically within the SESLHD hospital or campus but not necessarily a SESLHD run site but are external. **It is the researchers responsibilty to verify that the study's activity will be conducted within a SESLHD site and require a governance application to the SESLHD research office.**

Governance for multi-district projects

Multi-site projects that will pertain patient facing documents such as patient information and consent forms (PISCFs), a master document should be submitted to the lead HREC for approval within your application with designated blank spaces for the logos and other site-specific details for your site-specific versions to be submitted within the SSA. Please see the example below where the letterhead has a designated space within the master copy that will be submitted to the HREC committee for approval so that from the master PISC = site specific versions can be created inserting logos etc:


[Insert institutional letterhead]
[insert name of local institution/s where research is being conducted]

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Figure 6 - Master document letterhead

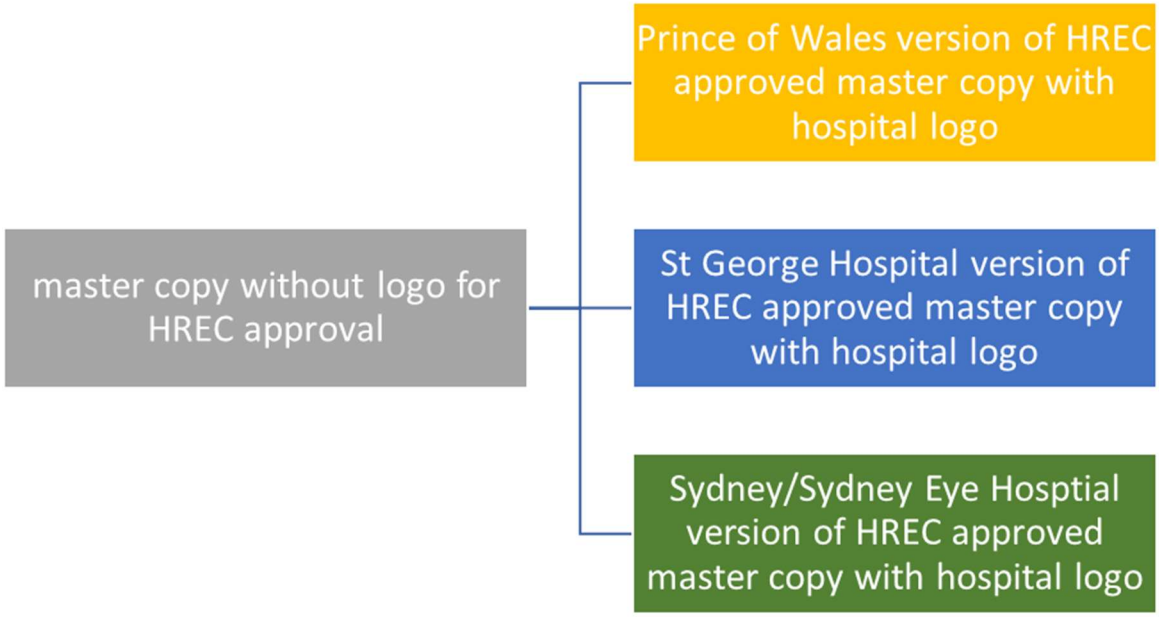


Figure 7 - Master copy to SESLHD sites

Please note that the SESLHD Research Directorate can only review and authorise Site Specific Applications (SSAs) for sites within its district. If your study is conducted over multiple districts, each Local Health District's research office will need to be approached for SSAs within their remit.

Please see the fictionalised diagram below to demonstrate an example:

-Dr Grey is the study's Coordinating Principal Investigator (CPI) and is also the Principal Investigator (PI) at POW where he works.

- Dr Grey is also conducting his study at St Vincent's hospital. He has obtained ethics approval for all sites (and all sites are cited on the HREC approval correspondence).

-A PI has been engaged from St Vincent's hospital and Dr Grey has sought SSA application and authorisation from St Vincent's hospital research office.

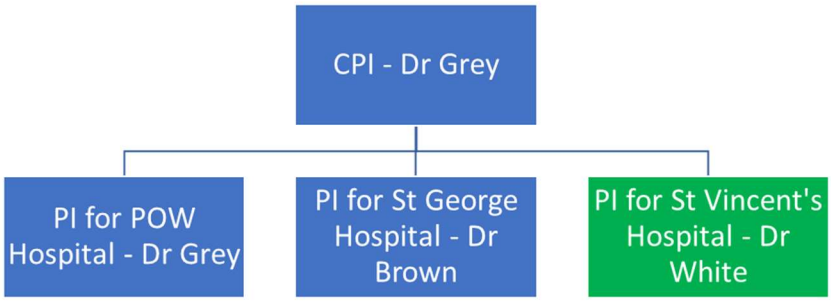


Figure 8 - Multi-district SSA map

External partners or sponsors?

Within your planning phase, the required agreements when conducting a study with external partners should be considered early in your project timeline but submitted within the SSA through REGIS. **All signatures from the research party should be collected before submission into REGIS and the Director of Research will be the last to sign the contract.**

SESLHD contract details are:

Business 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 Principal Investigator

What contract do I need?

CONTRACT	DETAIL	Commercial funding	Non-Commercial funding
CTRA standard	CTRAs are for commercially sponsored studies. As per PD2010_056 all clinical trials with an external sponsor must have a written agreement in place.	YES	NO
CTRA CRO	For a collaborative research study with an organisation acting as a local sponsor (i.e., for an overseas sponsor).	YES	YES
CTRA CRG	Clinical trials that are with Collaborative or Co-operative research group	NO	YES
Non-Clinical trial – collaborative agreement	For non-clinical trial studies that have collaborative parties	NO	YES
Form of Indemnity	For commercially sponsored clinical trials, the sponsor must provide an executed Medicines Australia Form of Indemnity.	YES	NO
Certificate of Currency of Insurance (with commercial funding)	For all commercially sponsored clinical trials, an Insurance Certificate must be submitted with the governance application. The insurance certificate should have: 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, section 2.2.(e)	YES	YES
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 an MTA	YES	YES

	may be required. Templates are available on request to the research office. Please note: if SESLHD is the donor of data of tissue to an external party = the SESLHD MTA template is required.		
Certificate of Currency of Insurance (non-commercial)	For non-commercial sponsors, please see the requirements here: PD2011_006 Clinical Trials: Insurance and Indemnity. 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).	NO	YES

*definition of a commercially sponsored trial in accordance to PD2011_006 -is a clinical trial where a commercial entity that is a pharmaceutical or device company: Initiates the trial and makes an application to conduct the trial under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Scheme administered by the Therapeutic Goods Administration; b) is directly funding the conduct of the trial, that is, making payments to the relevant hospital or investigator. This does not include trials where a commercial entity is providing in-kind support (e.g., provision of investigational product or funds) but has no other involvement in the conduct of the trial; and c) is the primary author or custodian of the clinical trial protocol.

Where can I access an agreement template?

SESLHD templates can be requested via the SESLHD-RSO@health.nsw.gov.au. Medicines Australia templates can be found on the SESLHD Research Website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines or https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/

Please see below the types of agreements that are processed within SESLHD Research Office within governance and signed by the Research Director on behalf of the health district are:

- Material Transfer Agreements (SESLHD MTA template- request via email)
- Standard forms of Indemnity (Medicines Australia Templates only)
- Form of Indemnity – HREC only (Medicines Australia)
- Service Level Agreements (SESLHD template – request via email)
- Multi-institutional Agreements (MIAs) and collaborative agreements
- Clinical Trial Research Agreements (Medicines Australia Templates only):
  CTRA standard
  CTRA CRO- collaborative research organisation acting as the local sponsor
  CTRA CRG - Collaborative or Co-operative Research Group (CRG) studies
  CTRA Phase 4 clinical trial (Medicines)
  CTRA Phase 4 clinical trial CRO (Medicines) contract research organisation acting as the Local Sponsor
- Non-Clinical Trial Collaborative Research Agreements (australianclinicaltrials.gov.au)
- Confidentiality agreements (CDAs, DOIs or NDAs)

Please note: Please ensure that contracts are planned early within your project phase and necessary signatures and organisational details are included **ready in advance**

for submission within your SSA application. This will streamline the process and the SESLHD Research director should be the last remaining signature required to fully execute the contract. There is a CTRA guide on the SESLHD website:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines

CTRA Guide

Please see the CTRA guide on the SESLHD research website:

https://www.seslhd.health.nsw.gov.au/sites/default/files/groups/Research%20Website/Policy%20%26%20Guidelines/CTRAguideMLB21072023.pdf or

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/governance

To avoid delays with CTRAs please ensure that you refer to the CTRA guide and note:

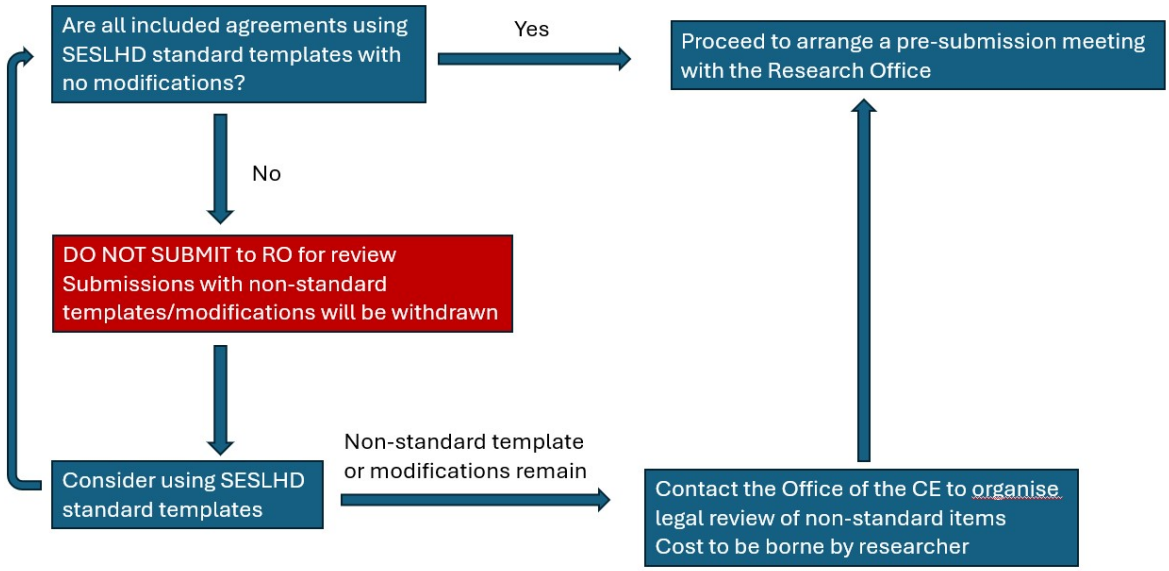
Schedule 2: all fees from SESLHD will be "**in accordance to current Ministry of Health Research Fee policy"**

Recruitment start and end dates can be difficult to estimate and adjust if delayed. Suggested wording to facilitate this rather than a fixed date:

START: Upon study activation at this site, defined as the date when all regulatory, ethical, and administrative approvals are in place and the site commences recruitment.
END: Upon completion of recruitment, defined as either the date when the target number of participants has been recruited or the recruitment period ends as specified in the trial protocol.

Non-standard templates submitted to SESLHD

The SESLHD research office does not have legal capacity to edit or modify clauses within agreement or contract templates, nor review or approve any modifications and editing of agreement templates. Review of non-standard templates can be sent to the district's executive office to facilitate legal review which will be at the cost and responsibility of the research team/principal investigator. To avoid delays and cost, we recommend utilising the available standard templates.



What is NaCTA (formerly SEBS)?

The panel reviewing Australian clinical trial agreements (previously known as SEBS) is now a national panel known as the National Clinical Trial Agreement (NaCTA) Panel. The NaCTA Panel is comprised of representatives from all states and territories.

Together with Medicines Australia the NaCTA panel have developed five Clinical Trial Research Agreements (CTRAs) as listed below, that are available for use by any sponsor and/or institution for specific clinical trial scenarios.

The NaCTA Panel has also developed standard Clinical Investigation Research Agreement (CIRA) templates with the Medical Technology Association of Australia (MTAA) = https://www.mtaa.org.au/clinical-investigation-research-agreements

***PLEASE NOTE**: Please ensure you are using the most current version of documents found on this page. The most recent version of the Clinical Trial Research Agreement – Medicines Australia Standard Form, was updated in 2017 and should have the title "Clinical-Trial-Research-Agreement-Medicines-Australia-Standard-Form-8-March-2017-b-2". Schedule 3.3 (1) and (8) should have the words "his or herself" replaced with "themselves/their"; and 4.10 where the text has been changed to "…written approval of the Sponsor." Using out-of-date forms may cause delays in executing CTRAs.

Please see the following website for more information: https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/

Will I need NaCTA approval?

Changes to the existing clauses in the body of the template CTRAs should go to NaCTA Panel for review.

Although review by the NaCTA Review Panel is not mandatory to amend the Schedule 4/Schedule 7 Special Conditions section, the service is recommended to assist clinical

trial sponsors with timely, standardised review, where only one negotiation is required, rather than several. Please check on the Medicine Australia website whether your CTRA will or will not require NaCTA review: https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/

Things to consider when filling the template:

(i) Third party payer: In accordance with clause 6.1, parties should use Schedule 2 to describe "the manner" in which the Sponsor will pay the Institution (i.e.: through a third-party payor). Institutions should ensure that invoices are made out to the Sponsor (with whom they have a contract) and sent "care of" the payor (who will pay the invoice).

(ii) Studies in which there is no product: In Schedule 1, parties should write in the 'Investigational Product' field: "There is no Investigational Product being used in this Study". Because the definition of Investigational Product (in Clause 1 'Interpretation') refers directly to the description in Schedule 1, entering such a description renders all obligations relating to Investigational Product in the body of the CTRA to automatically fall silent.

(iii) Collaborative Clinical trials supported by grant funding agreement: The Panel has worked with university partners to develop two variations of a set of clauses that can be used when a non-commercial sponsor receives grant funding for a trial through a Funding Agreement (from NHMRC, MRFF or Cancer Australia) and wishes to pass through some of those obligations onto the institution. The variations consist of clauses for each funder with the CRG CTRAs. The clauses are included in Schedule 4 in the usual way. Please see the clauses at: https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/

The website will also provide templates and initial contact point for submissions, submission closing dates and meeting dates for 2024.

CTN application details for SESLHD

For drugs that are not approved by the Therapeutic goods Authority (or TGA), a CTN will be required. Please see the website for information on how to apply online for the CTN: https://www.tga.gov.au/products/unapproved-therapeutic-goods/clinical-trials/faqs-ctn-online-submissions-and-clinical-trials-schemes

The CTN guide: https://www.tga.gov.au/sites/default/files/2024-03/clinical-trial-notification-ctn-form-user-guide.pdf

For the Australian Clinical trials handbook:

https://www.tga.gov.au/resources/guidance/conducting-clinical-trials-australia-using-unapproved-therapeutic-goods

For SESLHD details to include into the application:

Name of approving authority:

South Eastern Sydney Local Health District

Approving authority contact person:

Professor Georgina Hold

Approving authority contact position:

SESLHD Research Director

Approving authority contact phone:

02 9382 3152

Approving Authority Contact email:

SESLHD-RSO@health.nsw.gov.au

What online platforms should I use for study interviews and meetings?

Microsoft Teams and Pexip are the NSW Health-endorsed and supported platforms to conduct meetings and interviews with research participants. Telephone interview is also an option.

What is considered human tissue?

In accordance with The National statement on Ethical Conduct in Human Research - *Section 3: Ethical considerations in the design, development, review and conduct of research Chapter 3.2 Human biospecimens in laboratory-based research*: refers to any biological material obtained from a person including tissue, blood, urine and sputum; it also includes any derivative of these, such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person. For more information on the NSW Tissue Act 1983: please see NSW Health Guideline https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2023_008 : or Human Tissue Act legislation https://legislation.nsw.gov.au/view/html/inforce/current/act-1983-164#statusinformation and the national statement (Chapter 3.2): https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023

Training in Safe Transport of Infectious Substances by Air Course (Shippers Training Course)

The Safe Transport of Infectious Substances by Air Course (Shippers Training Course) has been compulsory since 1st July 2004. You are required by the International Air Transport Authority (IATA) and Civil Aviation Safety Authority (CASA) of Australia to ensure that you and your staff receive dangerous goods training on an approved course every 2 years.

Link to website: Safe Transport of Infectious Substances – Civil Aviation Academy (caaa.com.au)

Who is required to undertake this training?

The current government legislation requires that all those who pack, mark, label or complete the paperwork associated with the shipping of these items (i.e. dangerous goods) must be trained (classified as a Group F Employee). Therefore, for example, anyone who places a sample of the above in packaging, uses dry ice (or liquid nitrogen) as a refrigerant for any shipment (regardless of the content) or a flammable liquid must be approved by successfully completing this training.

This includes:

- researchers
- pathologists
- clinical trials staff
- laboratory managers and technicians
- stores personnel
- nursing staff and medical practitioners
- veterinary industry personnel to name but a few….

PLEASE NOTE: A Material Transfer Agreement is required between SESLHD and the external entity for the transfer of both tissue and/ or data. Please email the research office for the latest template SESLHD-RSO@health.nsw.gov.au

For access to tissue for research at the NSW Organ and Tissue Service

Please see their website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/organ-and-tissue-donation-service/research

What to do if you would like to retain human tissue for future use?

Retaining the human tissue after the completion of the study will require explicit consent from the participants and approval from HREC.
All future research activities beyond the project will require ethical approval before the samples can be used.
Participants should be made aware of the plan and provided with an option (such as a YES/NO tick box on the Consent Form) to consent or decline the request of storage and future use of their sample beyond this project.

Safe Waste Management

Please see the latest NSW government policy on waste management PD2020_049 including tissue.

Exporting any data from SESLHD?

For any data to leave the district, the SESLHD Data custodian must provide approval in alignment to NSW policy Directive PD2018_001.

Material transfer Agreement (MTA) versus Data Custodian Request (DCR)

Material Transfer Agreement (MTA) = is an agreement for the transfer of data and/or tissue from SESLHD to an external party.

Data Custodian Request (DCR) = is the process by which permission to export SESLHD data to an external party needs to be approved by the district's data custodian which is the Chief Executive. Please see the website for this process: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/data and request form and guide is here: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines

The **DCR** (data custodian request) template is a brief to be completed and signed by the Principal Investigator (the author) to the SESLHD Chief Executive (the SESLHD Data custodian). However, the template will first be pre-reviewed via the SESLHD Research Director before going to the Chief Executive for approval (see diagram below demonstrating the process flow). Please send completed brief templates within your SSA submission within REGIS. Please also include relevant documents to support your request with precise content details of the data being exported, such as the data dictionary, Protocol, survey questions etc. Protocol = Please demonstrate that the details surrounding data within your HREC approved version of the protocol aligns with the DCR request submitted.

DCR Templates can be found on the research website:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines

Please note: it is strongly recommended that within your project planning or pre-submission phase, you consider the design or methodology of your study to ascertain whether you are going to require identifiable, re-identifiable or unidentifiable data to leave SESLHD. Please ensure that you state the appropriate definition within your request for the Research Director and data custodian to review. Please see below for

examples. This request and approval process is to be submitted within your REGIS SSA submission.

Unidentifiable (individual identifiers have been permanently removed and by no means of which specific individual can be identified)

Re-identifiable (All identifiers are removed from the dataset e.g., name, postcode, date of birth), replaced with a code, or are aggregated. Re-identification may be possible if a master copy of data that contains identifiers or master copy of study participants is kept. Please ensure you are clearly identifying who is going to access the master copy and what measures will be taken to ensure its secure storage.

Identifiable The identity of an individual information, or other sensitive information, can be reasonably discerned. Please ensure that the risk and potential considerations such as sensitivity of the information is declared within the request.

How should I safely store my research data?

We recommend using NSW Health or Australian-based University hosted Teams/Sharepoint or OneDrive for data storage and collaboration. Multi-factor Authentication (MFA) should be enabled for highly sensitive data (e.g., identifiable or linkage data).
Local hard drive, removable media (e.g., USB and CD), other online platforms are NOT recommended storage options as they are either easy to lose and not regularly backed-up or lacking multiple data protection controls.

How long do I keep data for and how do I dispose of the records once that period has lapsed?

Please refer to*: State Records NSW General Disposal Authority GDA17_08.01.01 Research Management - Data collection and consents - conduct of clinical research Records relating to the conduct of clinical research*. This guideline includes records or documentation relating to the recruitment and consent of research participants, data/records/information access requests and approvals, the collection and analysis of data, preliminary findings, surveys, reporting and results:
Retention is for a minimum of 15 years after date of publication or completion of the research or termination of the study, then destroy.

A checklist and form need to be completed to document what records are authorised for destruction:

https://www.seslhd.health.nsw.gov.au/sites/default/files/documents/SESLHDPR220_0.pdf

Creating documents

Please ensure that site relevant patient facing documents have been created from the HREC approved master copy with appropriate hospital logo added.

For example:

All documents are to be titled with consistent information throughout documents i.e.: document saved filenames and titles to include versions and dates to match footers. **To avoid issues with study titles being too long and unable to be opened**– use the formula example for all document titles and footers as well as REGIS file names.

i.e.: [Regis reference] =*Year/(PID/ETH/STE) XXXXX – document type – version – date*

Please note: Please carefully select your documents. Uploading unnecessary or irrelevant files (namely within a zip folder), will require more time to triage and review, incurring process delays. To facilitate review – please ensure that each document is appropriately titled and uploaded into the correct category within the REGIS file.

Document types

Please utilise the templates on website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/research-forms-templates-guidelines

Please note: incomplete or incorrect documents will be returned for more information incurring delays to your timeline.

Ethics checklist

Governance checklist

Method of payment form

PISCF (if relevant) – with consent/revocation of consent

Protocol. Please be sure to include: -

- concise budget breakdowns for both financial and non-financial costs
- clear aim/objective
- the expected translational research impact within SESLHD
- Data collection sheet or data dictionary
- Cover letter (for studies without financial costs – will require to include non-financial or in-kind cost breakdowns). Failure to provide this – could cause delays in request for more information.

Logos

SESLHD staff (Principal Investigators) can access templates as well as the NSW Health logo for posters, fliers, posters, brochures etc through the intranet site: seslhd.health.nsw.gov.au/Forms_and_Templates/Templates

Intellectual Property arising from Health Research

All Intellectual Property created by an Employee in the course of their employment with the NSW Health Service is owned by the Public Health Organisation unless inequitable or pursuant to a contract.

- **We ask all research project to provide current and accurate notification in the SESLHD IP Notification Form to notify of any the creation, or anticipated**

imminent creation, of any work, product or process created in the course of their employment with SESLHD which may have, or which the PI believes may result in, the creation of Intellectual Property; at the time of submitting a Site-Specific (Governance) Application.

- All notification must be marked "confidential"; and forwarded to the SESLHD IP Committee for examination and consideration.
- After consideration of each notification, the Committee/ Central Support Service must make a recommendation to the Chief Executive of SESLHD for their approval as to whether any steps toward protection and/or Commercialisation of Intellectual Property notified to it is to be undertaken.
- We ask all projects to read the NSW Health Policy Directives - Intellectual Property arising from Health Research and familiarise themselves with the content.

Review of funding and costs

Each research study type will differ in funding and costs requiring varied types of documents to demonstrate financial detail, i.e.: large spreadsheet vs a cover letter stating small non-financial costs in-kind. However, please ensure that you have provided appropriate documentation of funding source, who will be managing the fund and a concise clear break down for both financial and non-financial (i.e.: in-kind) costs, in accordance with the National Statement:

> 5.3.7 A researcher should disclose the amount and sources or potential sources of funding for the research to the review body and, where appropriate, the participants. This information may include financial support, in-kind support, per capita payments or other payments or incentives provided by any entity supporting the research.

If there is insufficient detail, it will require a request for more information, causing delays in review and your timeline. If you require advice whilst planning your budget, please send an email to SESLHD-RSO@health.nsw.gov.au to the Research Business Manager.

PLEASE NOTE: If the amounts (both non-financial (in-kind) and financial) within the following documents listed below are not consistent or are not clearly stated **= The application will require further clarification and cause delay.**

- budget template
- Part E of SSA application
- CTRA (schedule 2)
- cover letter

SSA application Part E Site Costing and funding:

PLEASE NOTE: All research activity incurs a cost and all costs must be demonstrated within the application.

Non-financial i.e.: hours of (specific role) provided in-kind

Financial i.e.: the cost of hiring a position (award rate),

NOTE: ensure that all your costs and funding are consistent across the SSA application and the supporting documentation. Inconsistencies will incur delays in requesting clarification and or modification.

Queries:

Prior to sending an email = Please see the SESLHD Research Website:

https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home

AND / OR attend a drop-in session to speak directly with a research officer please scroll down on the website's front page: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home

Annual reports

Annual reports are required to be submitted to the lead HREC by the Coordinating Principal Investigator (CPI) and a governance milestone will be created for the district research office to acknowledge. Please see on the REGIS website instructions on how to submit an ethics annual report: https://regis.health.nsw.gov.au/media/1724/qrg-resapp-submitting-progress-final-report-milestone.pdf or https://youtu.be/V0KviU_w9VE?si=WvZOXvT_dnIrX-gb

For REGIS training on post approval management of your study please refer to the My health learning website: REGIS Post-Approval Fundamentals for Researchers & Coordinators (course code: 575990057).