SWSLHD REGIS Training Governance Requirements - STE Applications

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Please save questions for the end, as your question may be answered in this presentation ☺

Review/Approval Process for Research in SWSLHD

Ethical Review (HREA)

- Ethics Committee/Sub Committee (HREC)

Governance Review (SSA)

- Reviewed by Research Governance Officer (RGO)

Approved / Authorised to Commence

- Every study requires **approval** from the HREC and **authorisation** from the RGO

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Ethics vs Governance

Ethics:

- The what
- Theory
- Scientific merit and integrity
- Ethics committee review
- Ethical guidelines

Governance:

- The how
- Practical
- Finances/budgets
- Head of Department Support
- Local policy
- Research Directorate

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Creating a Project in REGIS

Logan Lown

Research Ethics and Governance Information System

Projects | Profile | Help | Sign out

Research Ethics and Governance Information System

Research Applicants

This home page will list below the 5 most recently registered projects you have access to as a project/application owner or other user who has been allocated shared access by that owner. Click on the listed project link to view details including associated ethics and site governance applications.

If you wish to: register a new project; continue an in-progress registration or view/manage other registered projects not listed below, select the 'Projects' icon in the gold bar at the top right of this page.

Other users - CE/Delegates, HREC Members, Dept. Heads, Ext. Reviewers

Depending on your role, you may have a couple of additional icons in the gold bar above such as 'Decision', 'Meetings' and/or 'Review' - if you have received notification that you have an activity to view in those areas, select the related icon to access the area you require.

Top 5 projects

2019/PID14037 SWSLHD Zip Test	Registered	12 Dec 2019

View all

Top 5 milestones due

There are no records to display.

Your activities

Projects

1 total

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Research Ethics and Governance Information System

Projects

REGIS is structured with the following hierarchy: Project>>>Applications>>>Post-approval/authorisation Amendments, Repor

In order to submit an application (ethics and/or site-governance), you must first register the project - you can do that here by sel

Project Registration will determine whether a new HREA is required for consideration by a HREC operating within ACT or NSV
details entered at registration pre-populate those subsequent applications.

Below are your projects. Click the link to open and manage your project.

+ New Project

Export CSV Show 10 entries

Title	Identifier	Status	Ethics approved	Expiry date

+ New Project

Select the form you wish to fill out:

Project Registration

Cancel

lications>>

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red for consideration by a HREC operating within ACT or NSW health services and if SSA will need to be generated
lications.

your project.

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New Project Registration

- Introduction
- Part A: Previous Ethics Application
- Part B: Project Details
- Part C: Research Site/s
- Part D: Coordinating Principal Investigator
- Part F: Upload Attachments
- Submit

Part C: Research Site/s

Preview | Save | Previous | Next

In the tabbed sections below, you will be required to nominate the sites at which you intend to undertake the activities for the project you are registering. Depending on the details of your project, you may need to enter sites under more than one tab.

You can ***add*** a site under the required tab/s by selecting the '+' icon. For locations with ACT Health or NSW Health, you will then select the relevant Centre/s and their associated site/s from pre-populated drop-down lists. For locations not operated by either government organisation, you will provide details as indicated.

If you wish to ***delete*** a site that you have listed below, select the tick box next to the Project Centre label and then select '-' in the gold bar below the section.

Before proceeding, please note: All PIs named in this section must have a REGIS user profile before you will be able to complete registration - as you enter the PI email address, REGIS will search for a match with a registered user.

If a match is found, their email address will display for you to select and their full name will be added below. As you progress, REGIS will prepopulate registration and subsequent applications with relevant details from their profile as required.

If no match is found, leave the PI email blank and select 'Invite to Register'. This will open a dialogue box for you to add the PIs username (email address) and, when you save the dialogue box to close, your PI will receive an invite to register in REGIS at the email address you've entered. Once they can confirm they have registered their profile, come back and complete your registration. In the meantime, select the next section to complete from the menu down the left-side of the page

Invite to Register

You must add at least one site in the below table.

If you are unsure of the Project Centre use this cell to search NSW/ACT site names in REGIS.
Once you select the Project Site the Project Centre will appear. Use this information to complete the table below.

Liverpool Hospital | South Western Sydney Local Health District

ACT Health | NSW Health | Other health jurisdictions or organisations

Nominate the project site/s within NSW Health and a Principal Investigator for each site
A research project may be conducted at one or more sites within one or more Centres within NSW Health.

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If you are unsure of the Project Centre use this cell to search NSW/ACT site names in REGIS.
Once you select the Project Site the Project Centre will appear. Use this information to complete the table below.

Liverpool Hospital

South Western Sydney Local Health District

ACT Health | NSW Health | Other health jurisdictions or organisations

Nominate the project site/s within NSW Health and a Principal Investigator for each site
A research project may be conducted at one or more sites within one or more Centres within NSW Health.
A 'Centre' may be a Local Health District (LHD), a Specialty Health Network, a Pillar organisation, an affiliated health organisation or other health organisation operated by NSW Health. A Site Specific Assessment (SSA) will be generated for each site nominated.

A Principal Investigator (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. In a single site research project or when a project does not require the appointment of a NSW Health principal investigator, the coordinating principal investigator may also be the principal investigator. The PI is the only person who has the authority to submit the Site application. An incorrect response here may cause the application to be Ineligible and will cause delay in processing.

If you are unsure of the names of the Centre or Site/s your project will be conducted at, **please discuss with your local research office. An incorrect selection here can delay your application process.**

Project Centre *: South Western Sydney Local Health District

Project Site *: Liverpool Hospital

Principal Investigator email (REGIS username) *: Logan.Lown@health.nsw.gov.au

Principle Investigator name: Logan Lown

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Project Registration Important Notes

The Project Registration cannot be edited after it has been completed.

All Public Health Sites within NSW need to be listed in the Project Registration to generate a SSA within REGIS

If you have forgotten to add a site, and the Ethics application has not been approved, you can add new sites through the New Site option.

If your Ethics Application has been approved, then an Ethics Amendment: Addition of New Site will need to be generated in REGIS first.

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Where to find the STE application in REGIS

Documents

History

Export CSV Show 10 entries Search:

Identifier	Title	Comments	Version	Status	Owner	Created date
2019/ETH12546	SWSLHD Zip Test		0.00	Submitted	Logan Lown	12/12/2019 03:48:00 PM
2019/STE15827	SWSLHD Zip Test		1.01	In Progress	Logan Lown	06/03/2020 09:36:18 AM
2019/STE15828	SWSLHD Zip Test - Campbelltown Hospital		1.00	In Progress	Malina Peng	12/12/2019 03:51:10 PM

Showing 1 to 3 of 3 entries

Previous 1 Next

All NSW Public Health Sites listed in the Registration or added as an Addition of Site Amendment will be listed here

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What’s in a SSA

- Part A – Project wide information
- Part B – Project team
- Part C – Departments and services
- Part D – Recruitment, records, tissue and data
- Part E – Site costing and Funding
- Part F – Attachments and site specific documents
- Part G – Declaration and request for HOD decision

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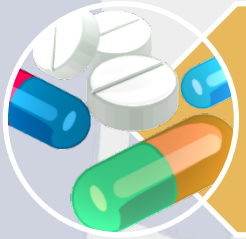
What to submit with your SSA

SWSLHD is the lead HREC

SWSLHD is not the lead HREC



Clinical Trials

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What to submit when SWSLHD is the lead HREC?

- If Ethics is approved, submit your Site Specific Documents
- Only submit the latest version of each document – do not keep earlier versions that are now outdated in REGIS.
- For investigators who are not employed by NSW Health and who will be working off-site, a Confidentiality Agreement is required.
- For Investigators who are not employed by NSW health who will also be coming on site, contacting participants or viewing identifiable information, a Criminal Record check is required **in addition** to the confidentiality agreement.
- If you have not filled in your REGIS Profile sufficiently, we will ask for a CV.
- Research Collaboration Agreement (If applicable)

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What to submit when SWSLHD is **not** the lead HREC?

- All ethics approval letters and subsequent amendments approvals
- HREC approval letter listing the SWSLHD site and principal investigator
- All MASTER Documents listed on HREC approval letters to be used at SWSLHD. If some documents are not being used at SWSLHD, please specify this in a cover letter to be uploaded in REGIS with the STE application.
- Confidentiality Agreement for all non-NSW health investigators
- Criminal Record Check for all non-NSW health investigators who will require access to the site for the duration of the study **in addition** to the confidentiality agreement.
- Research Collaboration Agreement (If applicable)

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What to submit for a Clinical Trial SSA

- All MASTER Documents listed in HREC approval letters
- GCP training for all investigators current within last 3 years
- Clinical Trials Research Agreement (CTRA) (from Medicines Australia website)
- CTN (Clinical Trial Notification) Documentation (if applicable)
- Medical Indemnity (if applicable) (from Medicines Australia website)
- Insurance documents (if applicable)
- SEBS approval letter for any changes to Schedule 4 or 7 of the CTRA
- Radiation Letter as submitted to HREC and the local SWSLHD Radiation Letter (if applicable).
- NSW Civil and Administrative Tribunal (NCAT) Approval (if applicable)

TIPS - Clinical Trial SSA

- We accept electronic or hardcopies of CTRA/Indemnity documents
- Ensure Correct Legal Entity details for SWSLHD
- Please ensure that the Sponsor and Principal Investigator has signed these documents prior to submission
- Good Clinical Practice Certification for all Investigators involved must be by a transCelerate approved provider.
  - https://praxisaustralia.com.au/
  - https://www.arcs.com.au/events/category/online-learning
- Refresher GCP Training: Self Directed Online Course
  - https://www.arcs.com.au/events/event/RGCPONLINE-NSWHEALTH
  - www.medicalresearch.nsw.gov.au/gcp-training/

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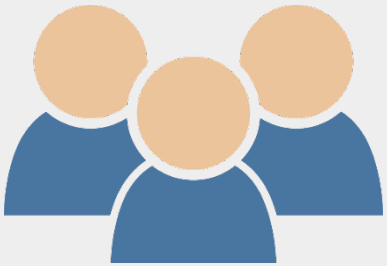
Additional SSA Requirements

- Pharmacy head of department support
- NSW Pathology quote
- Local site Radiation Safety Report (approved by lead HREC)
- Aboriginal Health & Medical Research Council (AHMRC) Ethics approval documentation (if applicable)
- NAATI Translated Documents (if applicable)
- Research Collaboration Agreement
  - If SWSLHD data is being transferred externally to SWSLHD
  - If funding from external sources/sponsor will be provided to SWSLHD for the purpose of the research

Preparing Site Specific Documents



- All research projects that require Participant Information Sheets and Consent Forms must have a MASTER version and a SITE SPECIFIC version. Additionally, any documents that will be provided to participants must be made site specific.

- All Site Specific Documents must:
  - Display the SWSLHD logo
  - Include all site specific information such as investigator names, contact details
  - Include the SWSLHD Research and Ethics Office complaints paragraph at the end of each ***Participant Information Sheet***
  - *Insert the local project number (2020/STExxxx) at the end of the complaints paragraph*

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Preparing Site Specific Documents

Ensure that the footer of all site specific documents contains **2** Versions numbers/dates

- The 1st should be the MASTER Version number/date which will be listed on the lead HREC ethics approval letter.
- The 2nd will be the SITE Version number/date which is the date that you create the site specific document (usually after the MASTER document has been approved by ethics)

Master Participant Information Sheet, Version 1.0, dated 1 January 2018

Bankstown Hospital Participant Information Sheet, Version 1.0, dated 30 August 2020

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Adding Head of Department

Part B: Site Team

Part C: Departments and Services

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

Identified against each nominated department.

Please note: the 'Head of Department' for any NSW Health staff undertaking roles of either PI or back-up PI (an Associate Investigator) for this project at this site must be listed in this section.

A pre-populated declaration of support for each nominated department head (including a complete copy of this SSA and its attachments) will be generated on completion of this SSA utilising the information in this section. Each Head will be notified by email of the need for them to respond to the support request you submit.
Therefore, it is also important that you have approached the department head before completing this application to discuss the project and what it is you are requesting them to support. Depending on the project, this may include but is not limited to: allocation of staff time; use of facilities and/or equipment and/or access to data/records. While some projects may be funded to support their activities, others may require in-kind support.

If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.

C1. Department *

No department head can be found for the selected department.

C2. Department Head Name

C4. Please state the resources (e.g. staff, service/s, investigations etc) you require this department to provide: *

Part C: Departments and Services

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

A pre-populated declaration of support for each nominated department head (including a complete copy of this SSA and its attachments) will be generated on completion of this SSA utilising the information in this section. Each Head will be notified by email of the need for them to respond to the support request you submit.
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If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.

C1. Department *

LIV - Clinical Information/Medical Records

C2. Department Head Name

Ashna Sharma

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TIPS - Head of Department Support

- Ensure that you select all the correct Head of Departments for your study.
- Please note that a supporting department (i.e. Intensive Care, Emergency department, Gastroenterology) does not have the jurisdiction to provide support for medical records access.
  - *If accessing participants Medical Records for the purpose of the study (this includes eMR and power chart, even if you already have access to these systems for clinical purposes) please the HOD for Medical Information in REGIS.*
- The HOD cannot be an investigator of the study as this is considered a conflict of interest. To avoid this, please provide this investigators in-line managers support in REGIS.
- If the correct Head of Department is not showing in REGIS and you cannot change this, please contact our office.

SSA – Status Flowchart

1. **In progress** – site specific application being complete/drafted

2. **Completed Pending HOD** - awaiting support from the HOD in REGIS.

3. **Submitted** – Once all selected HOD have provided support in REGIS, the SSA will automatically be submitted to the Research Directorate.

4. **Eligible /Ineligible** after administration checks are done.

5. If **ineligible**, follow *QRG – Resubmit a new version of the application after an ineligible notification*. The SSA will then go back to **submitted**.

6. **Information Requested –** If the Research Directorate requires further clarification. Please note that we require a response cover letter and updated documents in tracked and clean.

7. To submit further information, follow *QRG: Responding to a Request for Information – Initial Application*. Status will become **Information Provided**. This means it is with our office.

8. If the application is ready for approval as deemed by the Research Ethics Office, the SSA will be **Authorised**. You will receive an authorisation email via REGIS.

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Tips for Responding to a Research Governance Officer Request for Further Information

- You receive an email notification
- Locate your application in REGIS
- Create a new version of application
- Update Application form
- Provide requested documents in a combined ZIP file
- Please do not forget your **Response Cover Letter** (this applies to both ethics and SSA Responses)

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REGIS Tips!

- Please read the Quick Reference Guide if you are not familiar with using REGIS
- Please do not copy the application! Only create a **New Version** for replying to further information requests for both Ethics and SSA.
- Please do not forget your **Cover Letter** when responding to further information requests for both Ethics and SSAs.
- We recommend using Internet explorer or Google Chrome when uploading a ZIP file, as these are compatible with REGIS.

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Who do I contact?

Research Directorate

For: for assistance with registration, applications, and post-approval/authorisation matters such as: information/documents you need to include, missing or incorrect dep't information (site-governance applications), and how to use REGIS (non-technical).
Location – Level 2 UNSW clinical School – Liverpool Hospital
E-mail: SWSLHD-Ethics@health.nsw.gov.au
Website: http://www.swslhd.nsw.gov.au/ethics/
Phone: 02 8738 8304

REGIS

For: technical queries such as system issues or faults, and account access issues. The Help desk is available 7am-7pm Monday-Friday, excluding ACT Public Holidays.
Email: support@f1solutions.com.au
Website: https://regis.health.nsw.gov.au/
Phone: 1300 073 447

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Questions

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