Conducting Research at SWSLHD

Malina Peng

Administration Officer

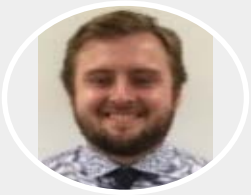
Research Directorate

NSW GOVERNMENT Health
South Western Sydney Local Health District

Research Directorate – Research Ethics and Governance Unit

- Research Ethics and Governance Manager
  - Dr. Shakti Shukla

- Research Ethics and Governance Coordinator
  - Dr. Cameron Lutman



- Senior Administration Officers
  - Mrs. Malina Peng
  - Mr. Logan Lown

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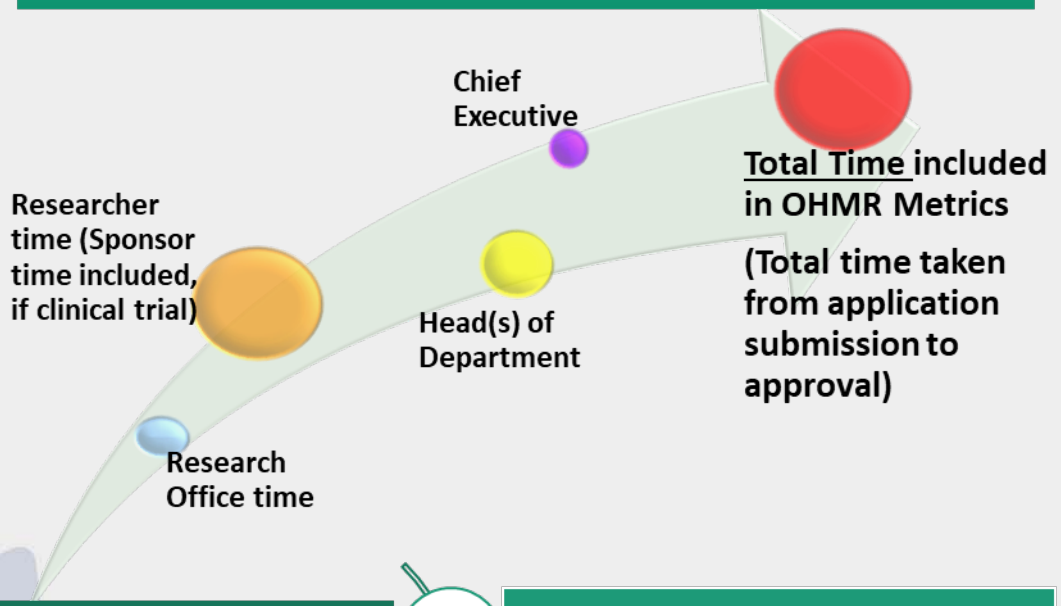
Overview

- Metrics from July 2021
- Decision Aid
- Low Risk Research
- Greater than Low Risk Research
- Research Ethics and Governance Information System (REGIS) – Project Registration, HREA and Site Specific Application

2023 Rollout of OHMR Metrics strategy

Implementation of OHMR Ethics and Governance metrics – Whole of Organization approach



OHMR mandated benchmarks* (since July 2021)

*Greater than low risk applications

- ***Ethics*** **- 90 Days**
- ***Governance*** **- 60 days**

Measures	Frequency of Reporting	Target		
		Not Performing	Underperforming	Performing
Metric 3 (KPI21-03) -- Ethics applications involving Greater than low risk to participants approved by the reviewing HREC within 90 calendar days (%)	Quarterly	<55%	≥ 55% and < 75%	Target of 75% met or better
Metric 4 (KPI21-04) – Site specific applications involving more than low risk to participants authorised within 60 calendar days (%)	Quarterly	<55%	≥ 55% and < 75%	Target of 75% met or better

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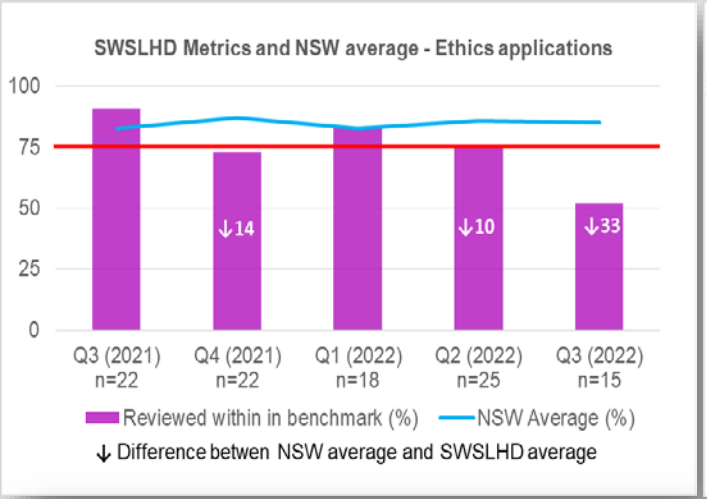
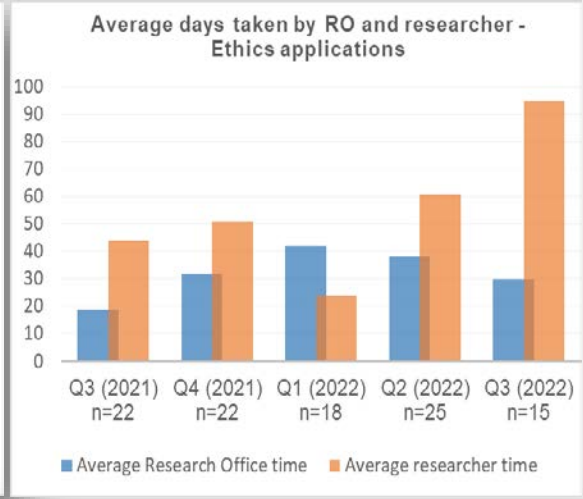
2023 Rollout of OHMR Metrics strategy

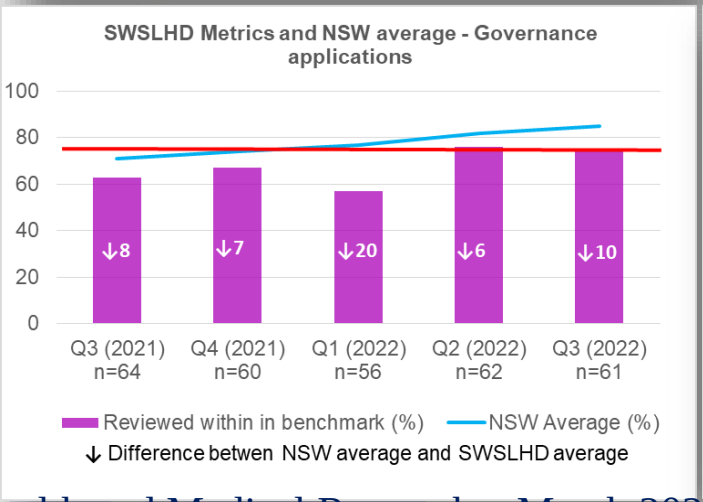
SWSLHD – Metrics Performance

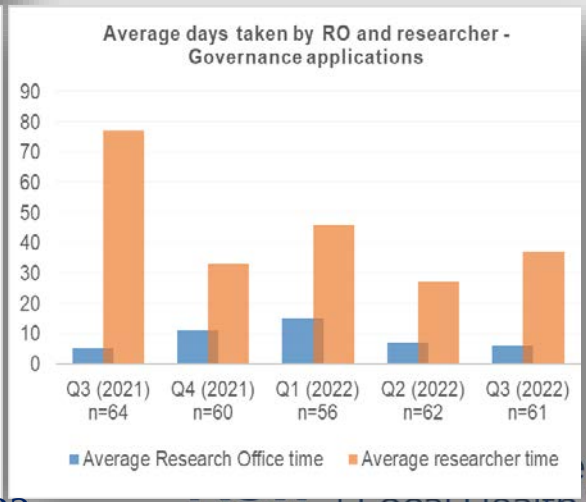
Target (red line) – 75%



Average time lapsed







Strategy for addressing metrics

- Research Office Strategies
  - Follow up with HREC review promptly
  - Process new applications and responses as soon as they are recieved
- Researchers Strategies
  - Follow up with HOD after a week
  - Respond to further information requests promptly
- Only submit your REGIS applications once you have all the required information/documents

Research Process Overview

Ethical Review (HREA)

- Reviewed by 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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Decision Aids

If you are not sure which pathway your research application falls upon, please fill out the Decision aid for review by our office.

Decision Aid:

- ✓ Complete the Decision Aid form
- ✓ Email the Decision Aid to SWSLHD-Ethics@health.nsw.gov.au with subject line: Decision Aid Review.
- ✓ The Research and Ethics Office will email you back within a week with a decision regarding what type of application you should complete.

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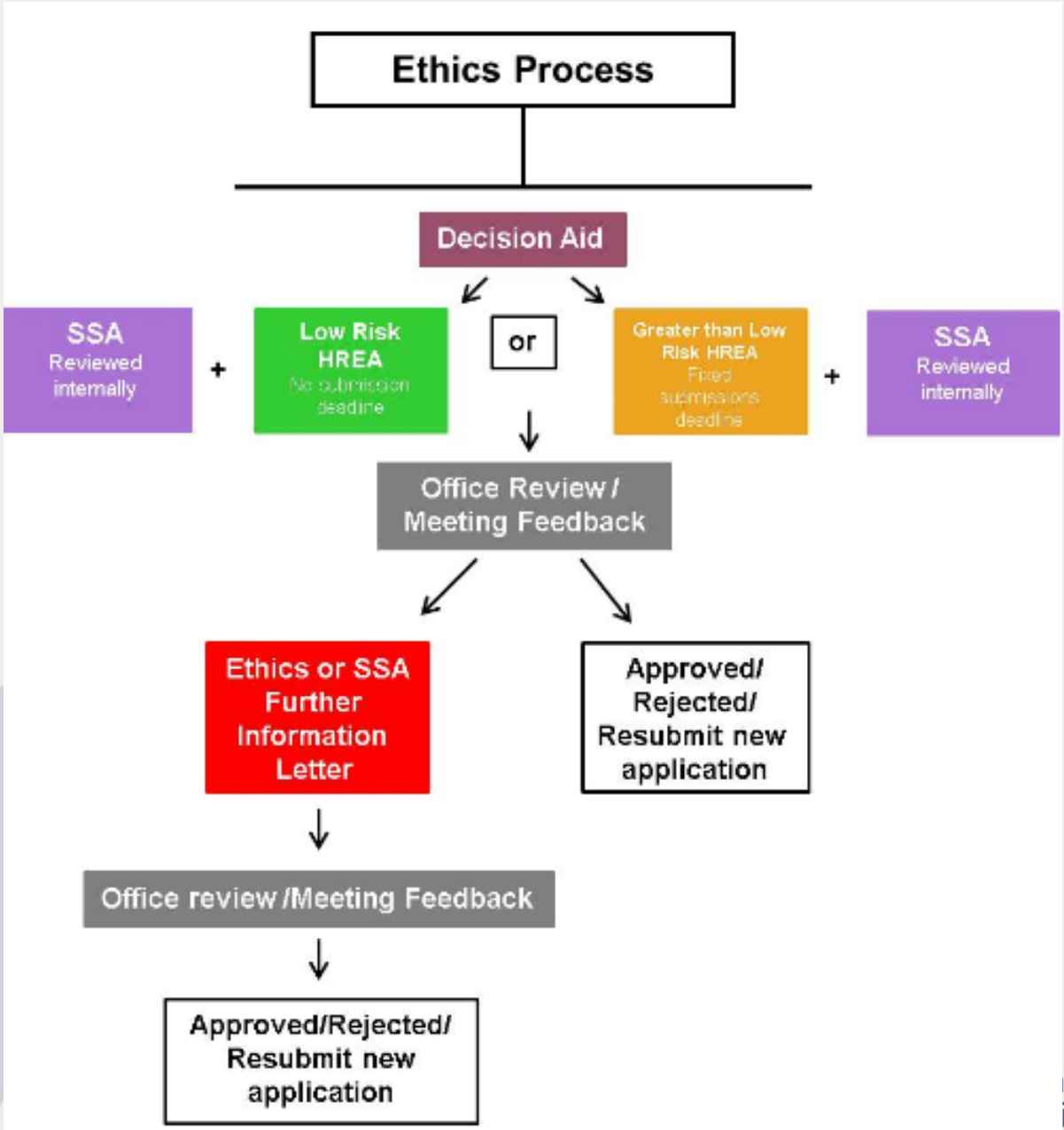

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Low risk research

Low risk and negligible risk research

- The expression ‘low risk research’ describes research in which **the only foreseeable risk is one of discomfort.**
- The expression ‘negligible risk research’ describes research in which **there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience**.
- Research in which the risk for participants is more serious than discomfort is not low risk.

Low risk research

Examples of low risk research pathway include:

- Retrospective audit
- Secondary use of de-identified data
- Low Risk Surveys and Focus Groups
- reviewed out-of-session by Executive Committee

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Greater than low risk research

Is research in which the risk for participants is more serious than discomfort and inconvenience.

Examples of greater than low risk research include:

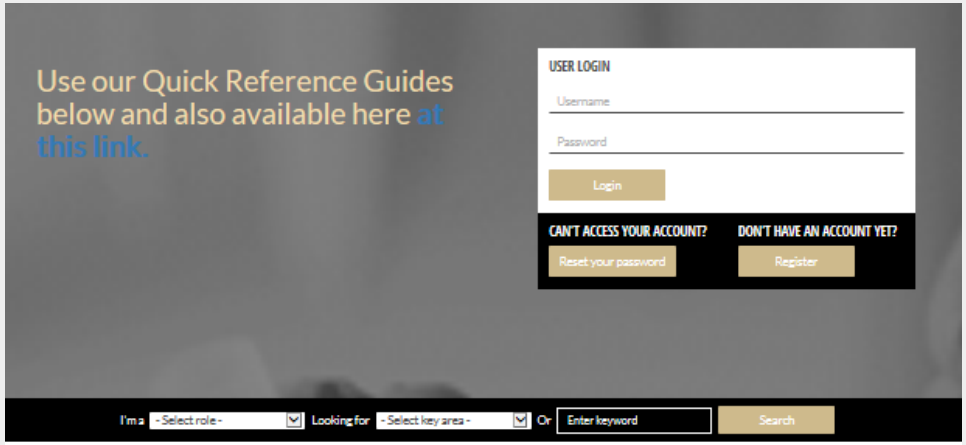
- Clinical Research
- Clinical Trials
- Qualitative Research: Some Surveys/Focus Groups/Interviews
- Studies involving Aboriginal/Torres Strait Islander Populations (must also obtain approval via AH&MRC)
- Vulnerable Groups

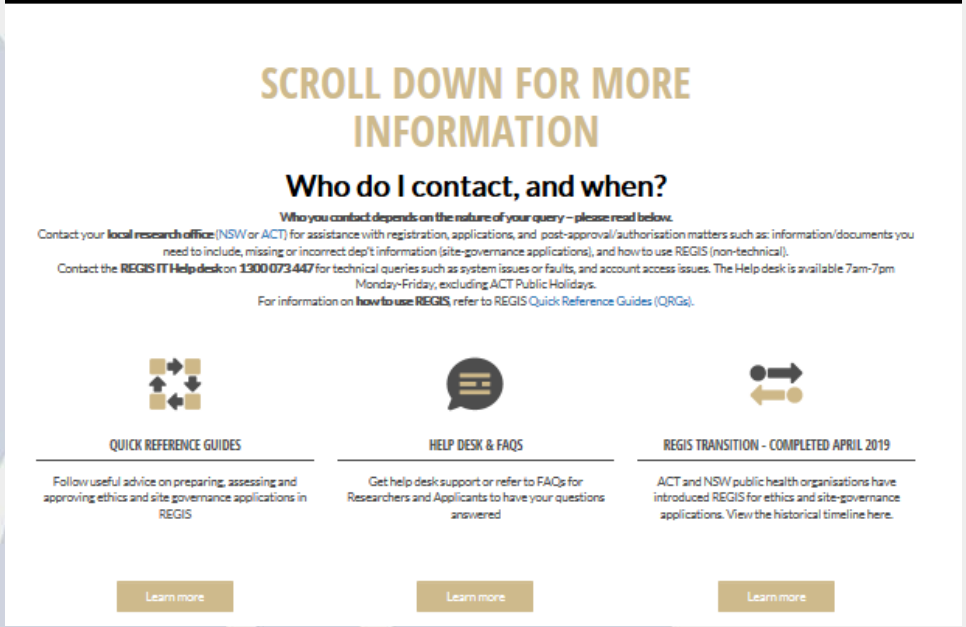


Greater than low risk research – Vulnerable Groups

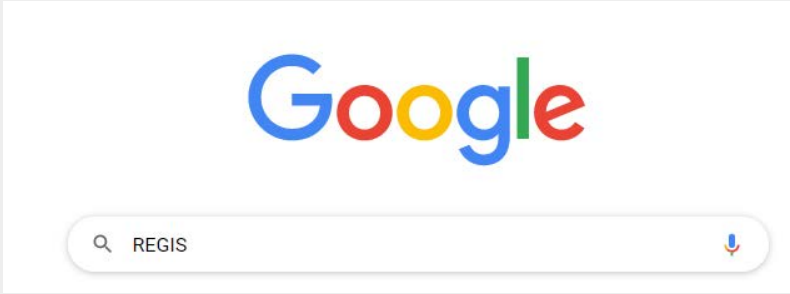
- Women who are pregnant and the human fetus
- Children and young people
- People in dependent or unequal relationships
- People highly dependent on medical care who may be unable to give consent
- People with a cognitive impairment, an intellectual disability, or a mental illness
- People who may be involved in illegal activities
- Aboriginal and Torres Strait Islander peoples
- People in other countries

Research Ethics and Governance Information System (REGIS)





REGIS



https://regis.health.nsw.gov.au/

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PROJECT Registration

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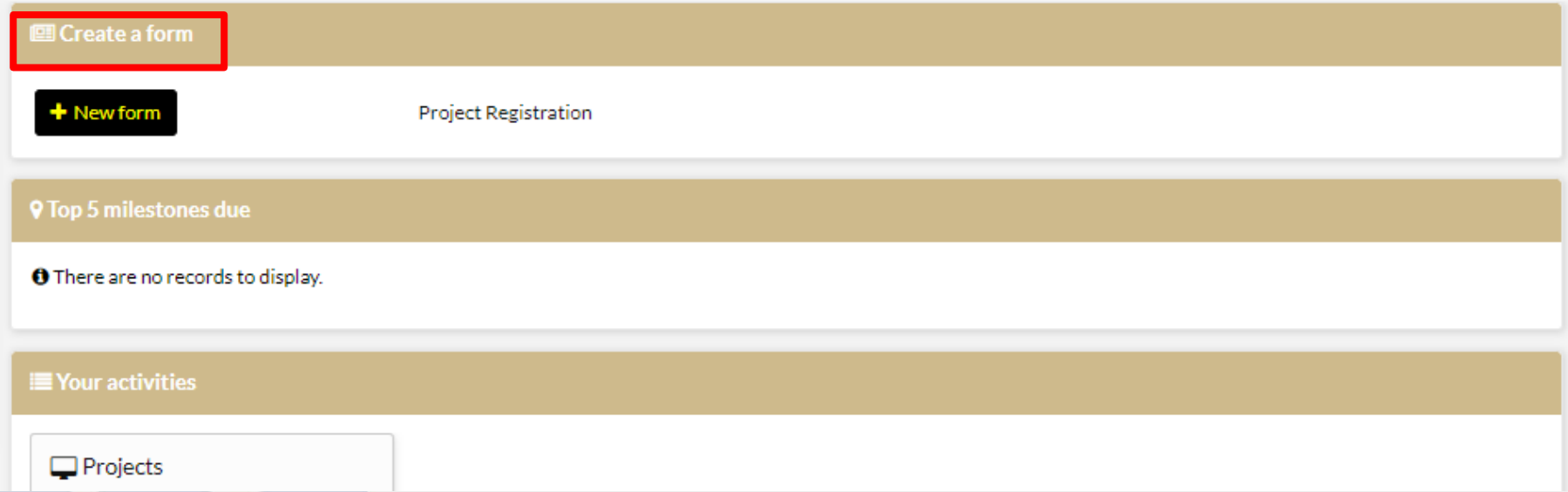
Creating a New Project



Click Project in top right corner, then New Form, then Project Registration.

You will need to register your project first, then REGIS will automatically generate the required HREA and SSA(s).

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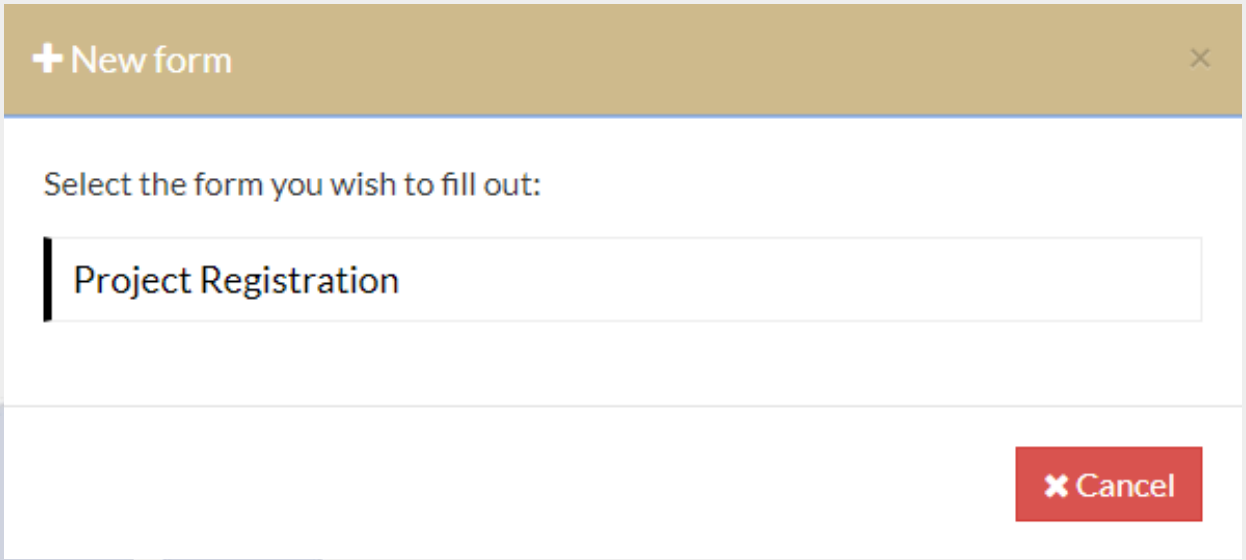
Creating a New Project



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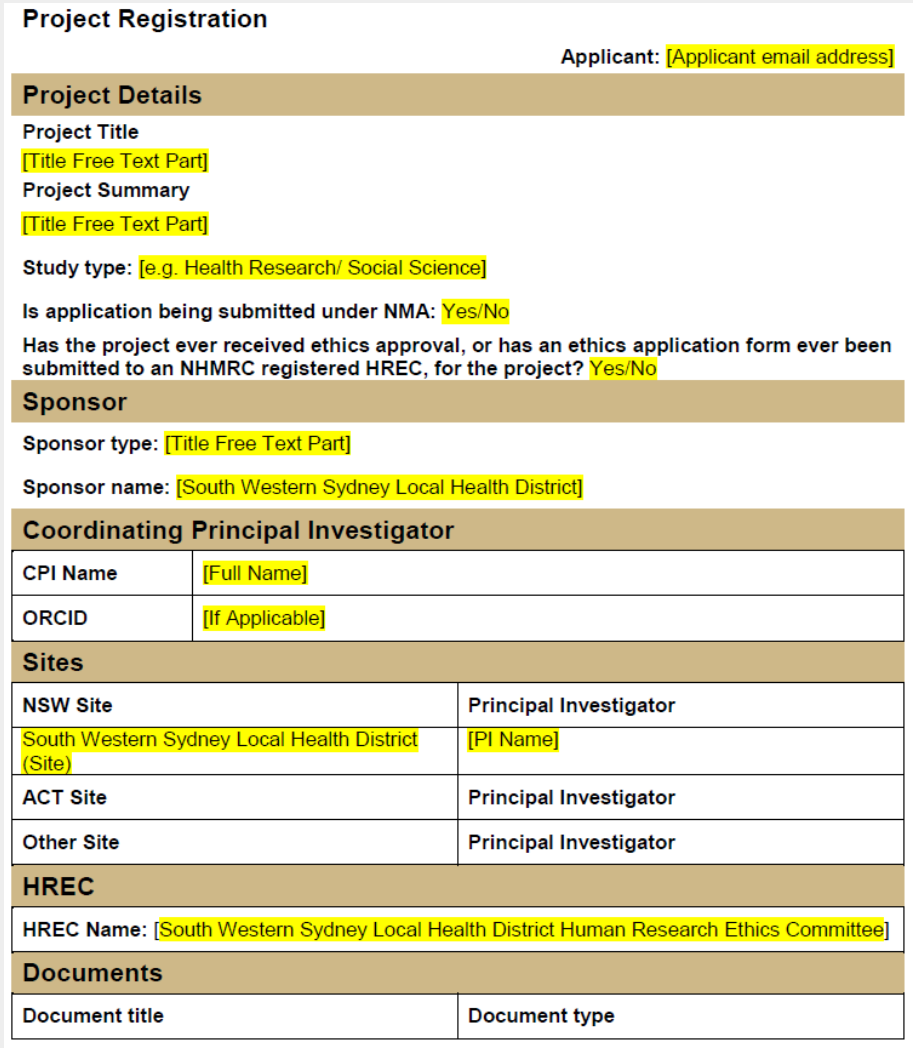
Project Registration

- Essential Reading: QRG – PROJECT REGISTRATION
- Ensure that the site and CPI and PI is correct.
- Additional to Ethics and SSA – but it is helpful as it AUTOPOPULATES information to save you time later.
- Ensure you list all SITES in NSW and ACT for the project!



Project Registration

Applicant: [Applicant email address]

Project Details

Project Title

[Title Free Text Part]

Project Summary

[Title Free Text Part]

Study type: [e.g. Health Research/ Social Science]

Is application being submitted under NMA: Yes/No

Has the project ever received ethics approval, or has an ethics application form ever been submitted to an NHMRC registered HREC, for the project? Yes/No

Sponsor

Sponsor type: [Title Free Text Part]

Sponsor name: [South Western Sydney Local Health District]

Coordinating Principal Investigator

CPI Name	[Full Name]
ORCID	[If Applicable]

Sites

NSW Site	Principal Investigator
South Western Sydney Local Health District (Site)	[PI Name]
ACT Site	Principal Investigator
Other Site	Principal Investigator

HREC

HREC Name: [South Western Sydney Local Health District Human Research Ethics Committee]

Documents

Document title	Document type

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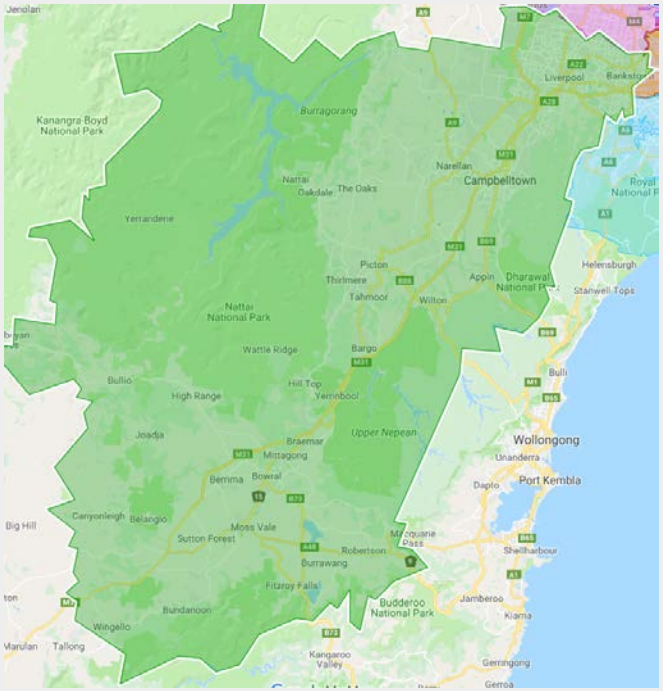
SWSLHD Sites



- Bankstown Lidcombe Hospital
- Bowral and District Hospital
- Camden Hospital
- Campbelltown Hospital
- Fairfield Hospital
- Liverpool Hospital
- Ingham Institute for Applied Medical Research
- South Western Sydney Local Health District (Site)
- Karitane
- NSW Service for the Treatment and Rehabilitation of Torture and Trauma Survivors (STARTTS)
- SWSLHD Community Health Centres

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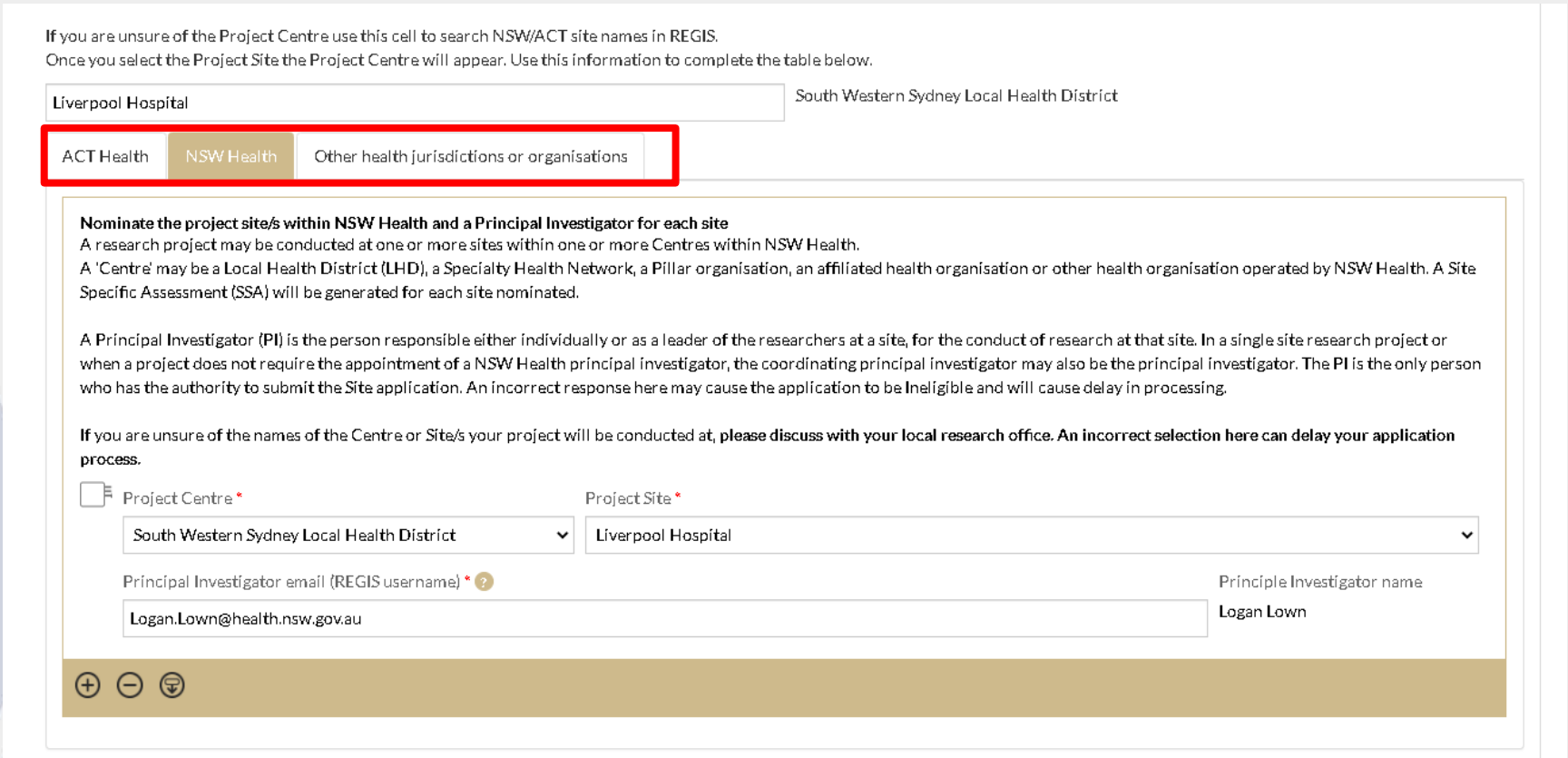
Example of selecting a site



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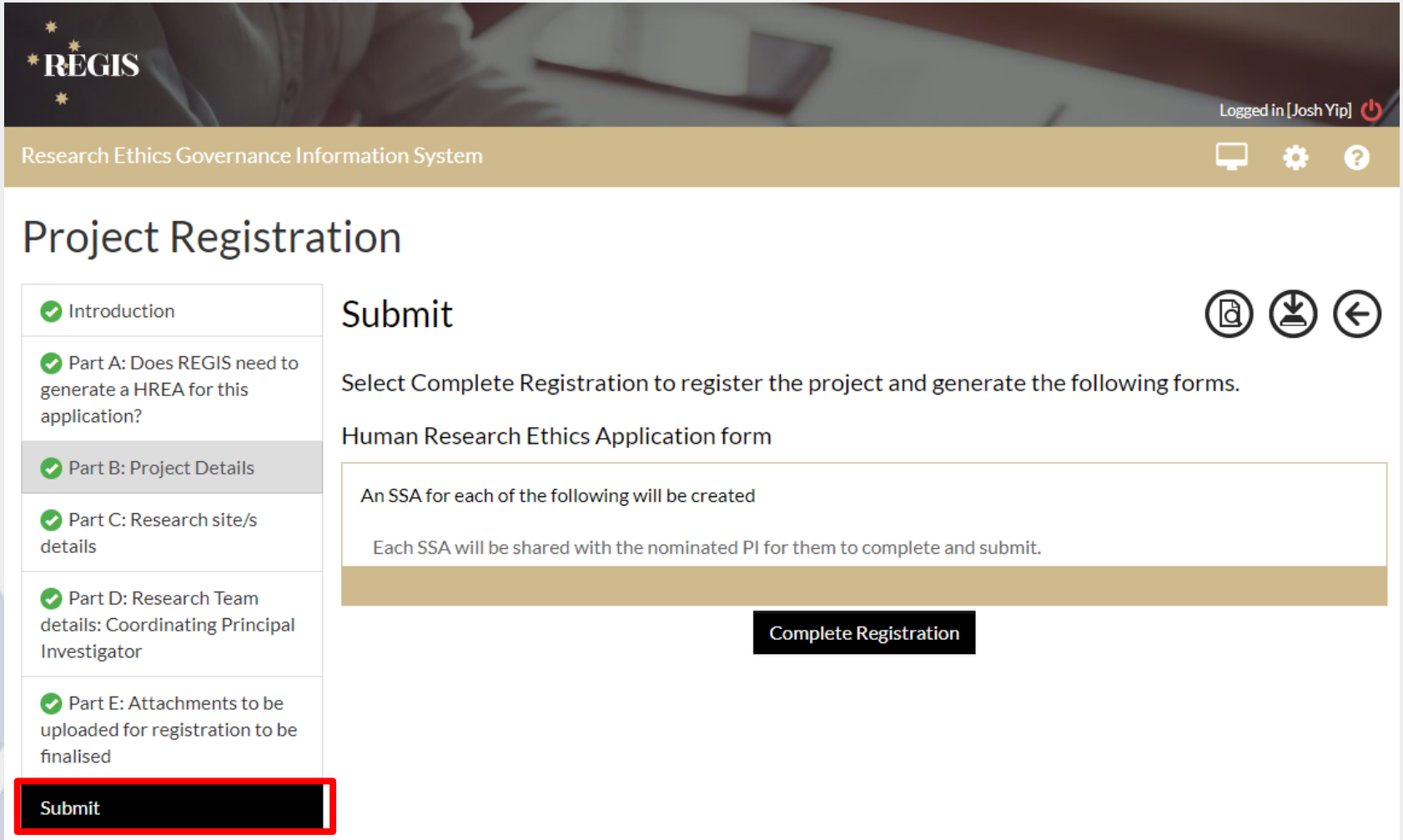
What about sites outside of SWSLHD?

- Ensure you list all sites to be involved in the project in your Project Registration.
- Private sites (i.e. private hospitals, private practices etc).
- SWSLHD HREC cannot provide ethical review for universities.



Part E: Attachments – draft protocol is fine. Submit Project Registration to get access to Ethics and SSA.

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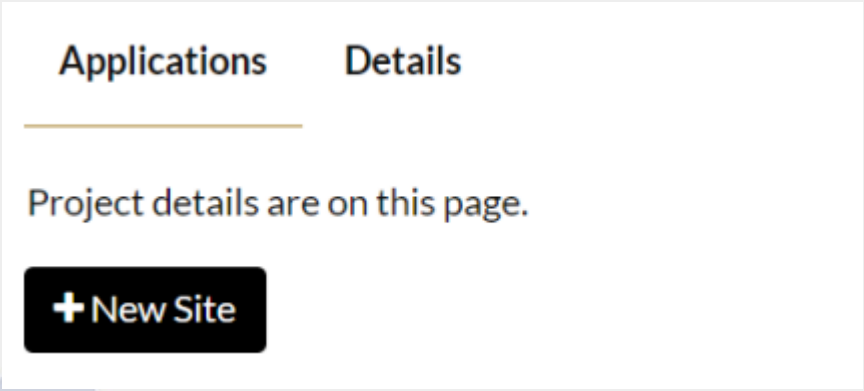
Submitted Project Registration but no SSA?

If a site was missed or incorrectly selected during project registration prior to ethics approval. If ethics status is ‘In Progress’



If not, create a new version of the ethics application and remember to update project team with new PI in HREA.

Identifier	Title	Comments	Version	Status	Owner
2019/ETH12546	SWSLHD Zip Test		0.00	Submitted	Logan Lown
2019/STE15827	SWSLHD Zip Test		1.01	In Progress	Logan Lown
2019/STE15828	SWSLHD Zip Test - Campbelltown Hospital		1.00	In Progress	Malina Peng

Same process if it is an NMA study.

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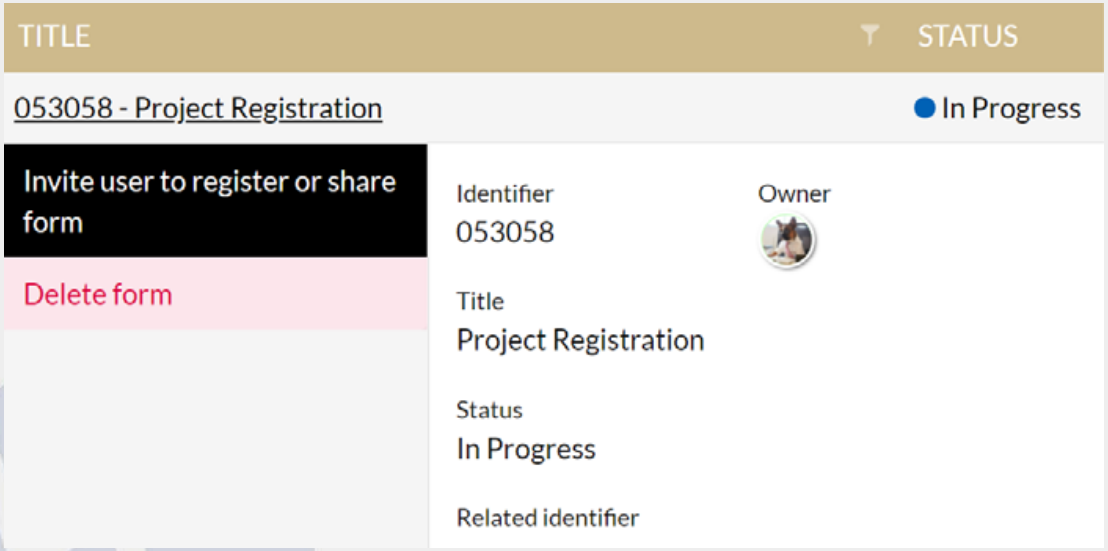
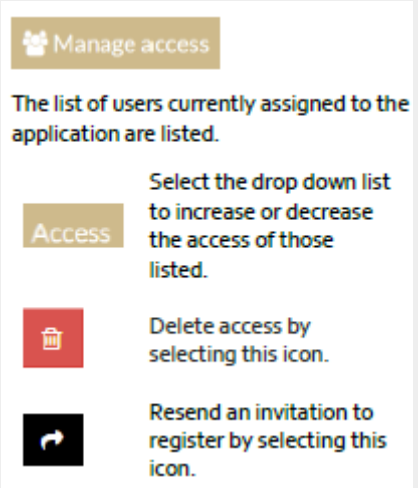
Edit Access





The 'Invite user to register or share' wizard will pop up.

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Terms in REGIS

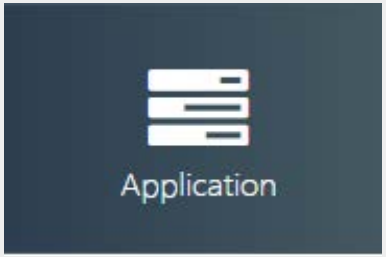
Project Reference # = 2023/PIDXXXXX

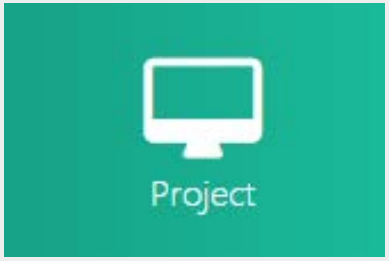
Ethics Reference # = 2023/ETHXXXXX

Site Specific Reference # = 2023/STEXXXXX

Application = Pre approval documents

Project = Post approval documents





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Human Research Ethics Application (HREA)

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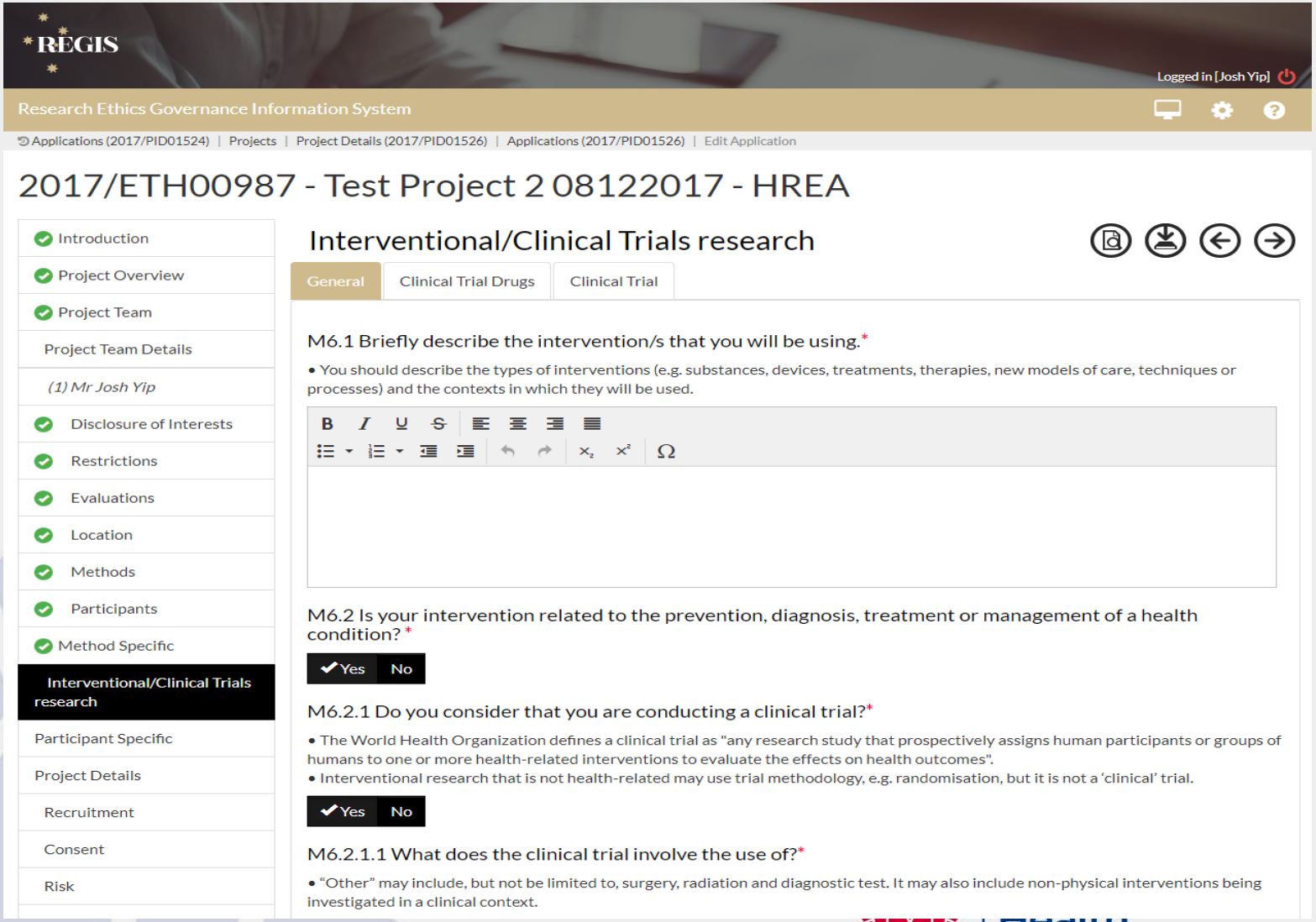
Greater than Low Risk Application
HREC MEETING DATES FOR 2023

Please refer to our website for yearly updates:

Submission Closing Date	HREC Meeting Date
Friday, 3 February 2023	Monday, 20 February 2023
Friday, 3 March 2023	Monday, 20 March 2023
Friday, 31 March 2023	Monday, 17 April 2023
Friday, 28 April 2023	Monday, 15 May 2023
Friday, 2 June 2023	Monday, 19 June 2023
Friday, 30 June 2023	Monday, 17 July 2023
Friday, 4 August 2023	Monday, 21 August 2023
Friday, 1 September 2023	Monday, 18 September 2023
Friday, 29 September 2023	Monday, 16 October 2023
Friday, 3 November 2023	Monday, 20 November 2023
Friday, 24 November 2023	Monday, 11 December 2023

Example of an Ethics Application



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Project Team Details – Section 1

CPI – This person will be the first person in the table. If this person is also a site PI they will appear multiple times – **do not remove them.**

The person listed as **CPI** must have the following response in HREA (this has been prefilled).

1.9.4 MUST use REGIS username/email

1.9.10 MUST be Coordinating Principal Investigator

PI/s – Site PI/s added at Project Registration will appear under the CPI

Administration contact - If you would like to add an administration contact to the ethics application who is not already listed in the table, add another line with their Title, Name and Surname on the previous page, 'Project Team'.

Ensure that you list all investigators in both the HREA and the protocol.

Attachments

- Protocol – mandatory document. Template available on our website which is endorsed by the SWSLHD HREC.
- MASTER documents – Participant Information Sheet, Consent Form and Withdrawal Form.
- Any other supporting documents Flyer/Brochure etc.

Protocol Tips

Provide a substantial Protocol for review ensuring that it has the following information:

- A footer that lists the name of the document, version number and date – page numbering is recommended.
- The rationale/background must have references
- waiver of consent is well justified
- Ensure that Ethical Considerations are listed in the Protocol
- Ensure that data collection items are listed in the protocol it the study is a retrospective review.
- Appendices are not acceptable – all documents must be provided individually with its own footer.

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MASTER documentation

The Participant Information Sheet/Consent form **should not** refer to site specific information. Please ensure that all master versions:

- Do not display the SWSLHD logo; and
- Do not have any site specific information such as the site name, investigator names, contact details, etc; and
- Display in the following in the footer: the name, version and date of the Master document, e.g.
  Master Participant Information Sheet, version 1.0, dated 1 January 2022

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ETHICS - Tips

- Version control e.g. Document title, version number and date.
- State Specific requirements for sites that involve WA/VIC.
- Edit Access can edit application however only CPI and Principal Investigator (PI) must submit the final applications in REGIS.

Common issues, mistakes and omissions

- Version control and missing footers on all documents
- Updated documents provided in tracked and clean
- One third of the applications consists of grammatical and spelling errors
- HOD support – study team members are not allowed due to Conflict of Interest

ETHICS – Status Flowchart

1. Submitted
2. Eligible / Ineligible
3. If ineligible, follow *QRG – Ineligible Notification – Resubmitting Application*. The HREA will then go back to submitted.
4. Under Review/Assigned to meeting
5. Information Requested . Please note that we require a response cover letter and updated documents in tracked and clean. Please respond within set timeframe for compliance with OHMR Metrics.
6. Information Provided
7. Approved/Not Approved.

Site Specific Application

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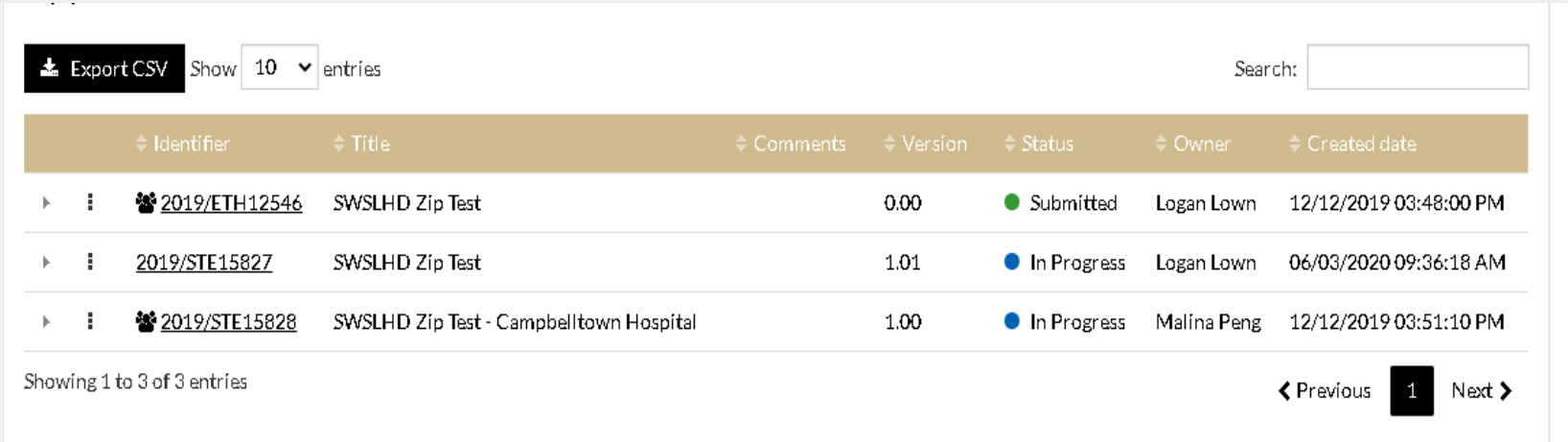
Submitting an SSA Application



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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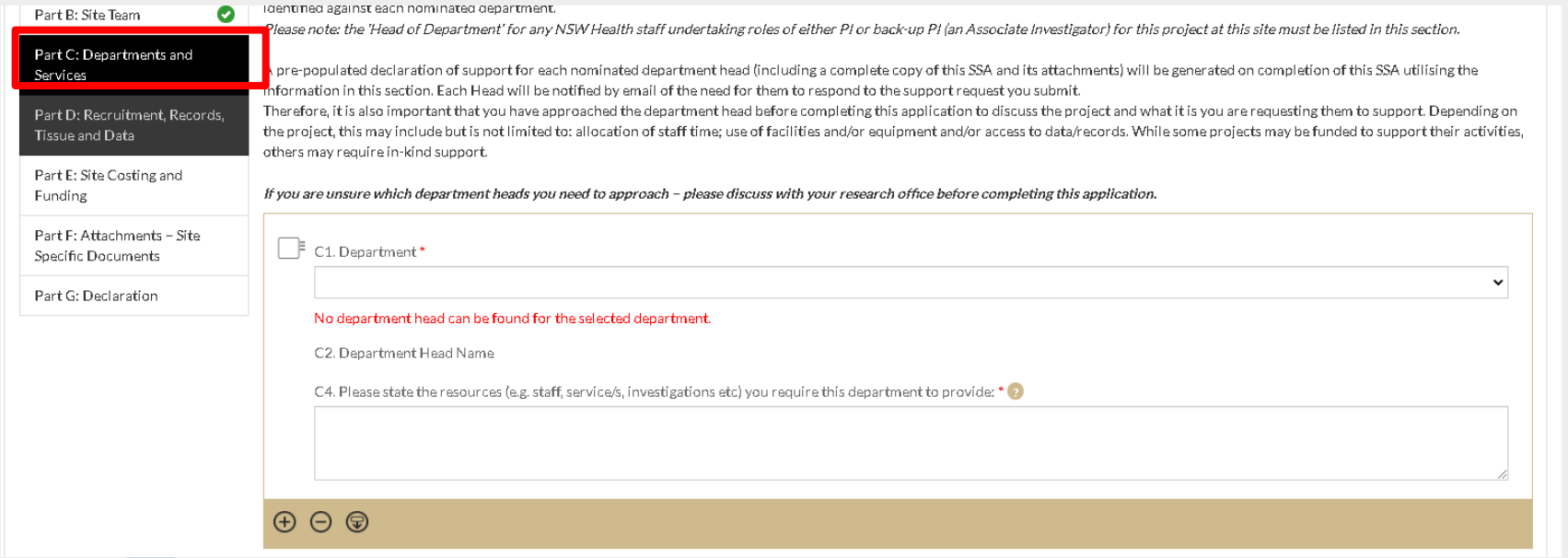
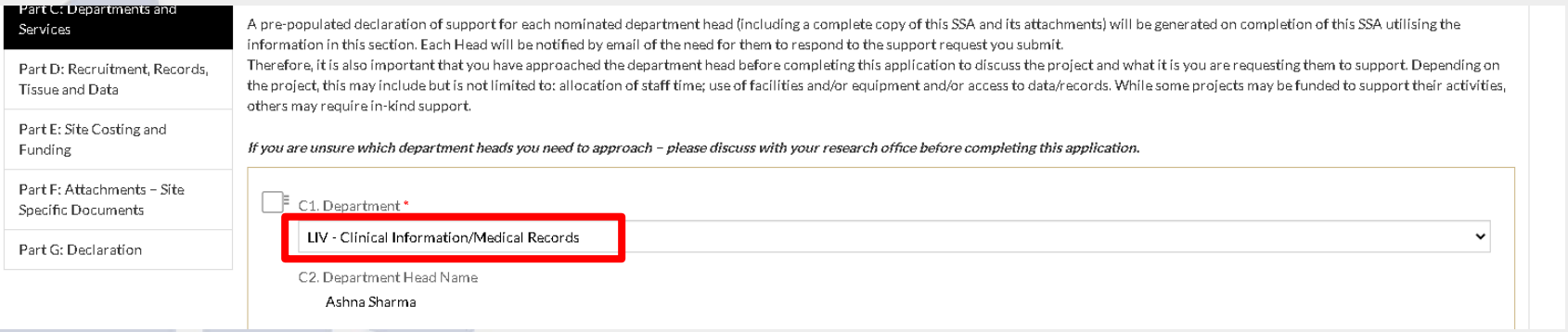
Adding Head of Department





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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.
- The HOD cannot also be an investigator of the study as this is considered a conflict of interest. To avoid this, if a HOD is an investigator please provide this HODs 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 via email.

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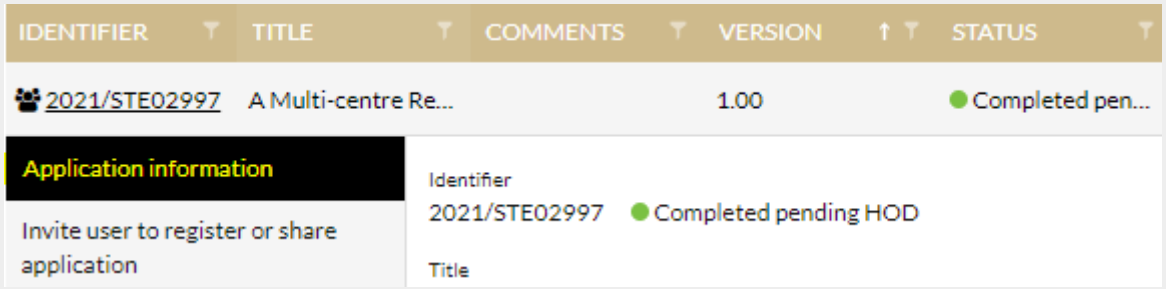
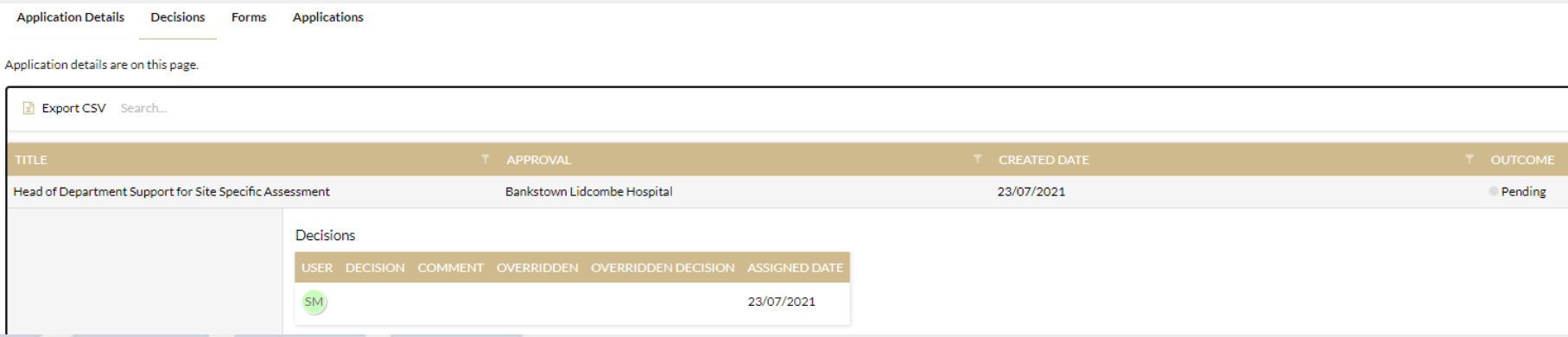
How to check outstanding HODs in REGIS





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Frequently Asked Questions

My Application is "HOD not supported" how can I find which HOD has not supported?

To see which HOD has or has not yet made a decision and any comments provided, follow the steps outlined in the previous slide. In summary, click on the STE row, then select application information. Once the page has loaded, click on Decisions tab and select Head of Departments.
Please create a new version to edit the SSA if required to resolve HOD issue.

Will the Site application go back to all HOD(s) upon resubmission?

No, any HOD that has previously provided a decision of either supported or not supported **will not be asked to provide support again**, only additionally added HOD(s) will be required to provide support.

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SSA – Status Flowchart

1. **Completed pending HOD/HOD not supported**

2. **Submitted** when you submit the SSA.

3. **Eligible/Ineligible**

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

5. If further clarification is needed, SSA will either be **Information Requested**. Please note that we require a response cover letter and updated documents in tracked and clean. Please respond within set timeframe for compliance with OHMR Metrics.

6. Submit further information, and the status will become **Information Provided**. This means it is with our office.

7. 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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What you need to submit with SSAs

- All MASTER Documents listed on HREC approval letters to be used at SWSLHD.
- All ethics HREC approval letters and subsequent amendments approvals
- Site Specific Documents based on the latest approved master version.
- Only submit the latest version of each document
- Confidentiality Agreement for investigators not employed by NSW Health. Criminal Record check (within 3 years) if they are also coming on-site, contacting participants or viewing identifiable information.

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Additional SSA Approvals (if applicable)

- Medical Records Head of Department support
- 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
- NSW Civil and Administrative Tribunal (NCAT) Approval
- Translated documents approved by a NAATI translator
- 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

Clinical Trial SSA requirements

- Evidence of Good Clinical Practice (GCP) training for all investigators conducted within last 3 years.
- Clinical Trials Research Agreement (CTRA) (from Medicines Australia website)
- Southern & Eastern Border States SEBS approval letter for any changes to Schedule 4 or 7 of the CTRA
- Medical Indemnity (if applicable) (from Medicines Australia website)
- CTN (Clinical Trial Notification from the TGA) (if applicable)
- Current insurance certificate (if applicable)

CTRA/Indemnity documents

- We recommend electronic signature for CTRA/Indemnity documents.

- Ensure Correct Legal Entity details for SWSLHD:

South Western Sydney Local Health District
Administration Building, Eastern Campus, Liverpool Hospital
Locked Bag 7279, Liverpool BC 1871, ABN: 46 738 965 845

- Please ensure that the Sponsor and Principal Investigator has signed these documents prior to submission in REGIS.

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Preparing Site Specific Documents

- All Site Specific Documents must:
  - Display the SWSLHD logo
  - Include all site specific information such as investigator names, contact details, relevant site information
  - Include the SWSLHD Research Directorate complaints paragraph at the end of each ***Participant Information Sheet*** and insert the local project number (20XX/STEXXXXX).
  - Display the name, version number and date of the document in the footer of the Site Specific Document IN ADDITION to the Master footer, e.g.
    Liverpool Hospital Participant Information Sheet, version 1.0, dated 30 January 2023
    Master Participant Information Sheet, version 1.0, dated 1 January 2023

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Who do I contact, and when?

Contact the Research Office

For information on:

- what to include in your REGIS application(s)
- the status of your REGIS application(s)
- how to use REGIS
- **Phone: 8738 8304 or 8738 8314** | Email: **SWSLHD-ethics@health.nsw.gov.au**

Contact the REGIS Technical Help Desk (Monday - Friday, 7AM to 7PM, excluding ACT Public Holidays):

For any technical issues with REGIS including, but not limited to:

- system issues or faults
- account access issues
- system advice (your research office may also be able to help you)
- Phone: 1300 073 447 | Email: support@f1solutions.com.au

Contact the NSW eHealth REGIS Support Team (Monday - Friday, 9AM to 4PM, excluding NSW Public Holidays):

For any non-technical issues with REGIS including, but not limited to:

- information on training, resources and news
- feedback on using REGIS
- general REGIS 'How to' questions
- Email: regis@health.nsw.gov.au

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Questions

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