

# Conducting Research at SWSLHD

**Malina Peng**

**Administration Officer**

**Research Directorate**



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# Research Directorate

- Research Ethics and Governance Manager –  
**Jessica Grundy** *(oversee all office functions including HREC, Research Governance and Research Contracts)*
- Research Ethics and Governance Coordinator –  
**Andrea Lee** *(HREC and Research Governance)*
- Senior Administration Officers
  - **Malina Peng** *(HREC and Research Governance Administration)*
  - **Logan Lown** *(HREC and Research Governance Administration)*



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# PROJECT

# Registration



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# Research Ethics and Governance Information System (REGIS)

Use our Quick Reference Guides below and also available here [at this link](#).

**USER LOGIN**  
Username  
Password  
Login

**CAN'T ACCESS YOUR ACCOUNT?**  
Reset your password

**DON'T HAVE AN ACCOUNT YET?**  
Register

I'm a  Looking for  Or  Search

**SCROLL DOWN FOR MORE INFORMATION**


**Who do I contact, and when?**

Who you contact depends on the nature of your query – please read below.

Contact your **local research office** (NSW or ACT) for assistance with registration, applications, and post-approval/authorisation matters such as: information/documents you need to include, missing or incorrect dept information (site-governance applications), and how to use REGIS (non-technical).

Contact the **REGIS IT Help desk** on **1300 073 447** 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.


For information on **how to use REGIS**, refer to REGIS Quick Reference Guides (QRGs).



**QUICK REFERENCE GUIDES**

Follow useful advice on preparing, assessing and approving ethics and site governance applications in REGIS


[Learn more](#)



**HELP DESK & FAQs**

Get help desk support or refer to FAQs for Researchers and Applicants to have your questions answered

[Learn more](#)



**REGIS TRANSITION - COMPLETED APRIL 2019**

ACT and NSW public health organisations have introduced REGIS for ethics and site-governance applications. View the historical timeline here.

[Learn more](#)

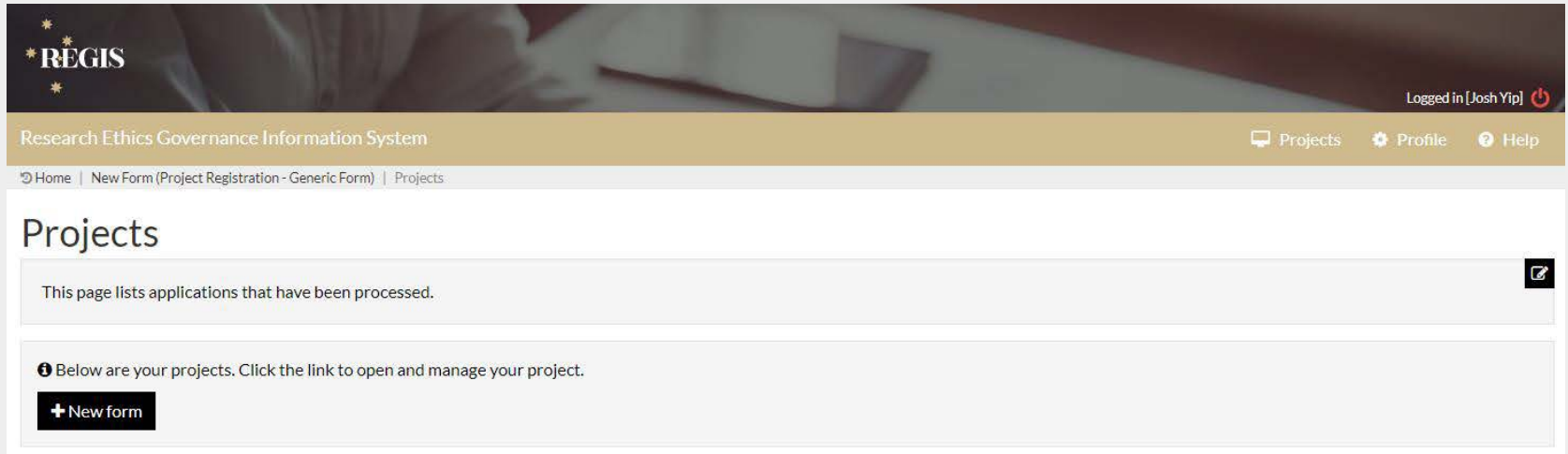


Google 'REGIS'  
<https://regis.health.nsw.gov.au/>



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# Creating a New Project



REGIS

Research Ethics Governance Information System

Logged in [Josh Yip]

Projects Profile Help

Home | New Form (Project Registration - Generic Form) | Projects

## Projects

This page lists applications that have been processed.

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

[+ New form](#)

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

+ New form

×

Select the form you wish to fill out:

Project Registration

×

 Cancel

# Project Registration

- Essential Reading: QRG – PROJECT REGISTRATION
- Ensure that the site and CPI and PI is correct. Don't worry too much about the documents at the stage.
- 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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# Project Registration


 Introduction

 Part A: Does REGIS need to generate a HREA for this application?

 Part B: Project Details

 Part C: Research site/s details

 Part D: Research Team details: Coordinating Principal Investigator

 Part E: Attachments to be uploaded for registration to be finalised

**Submit**

## Submit



Select Complete Registration to register the project and generate the following forms.

### Human Research Ethics Application form

An SSA for each of the following will be created

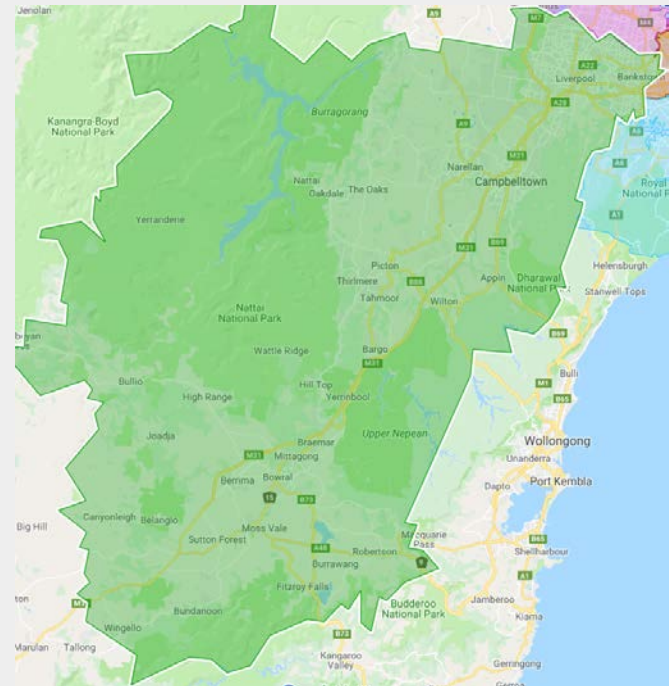
Each SSA will be shared with the nominated PI for them to complete and submit.

**Complete Registration**



# SWSLHD Sites

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



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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. SWSLHD HREC has accreditation to approve for any Public Health Organisation site under National Mutual Acceptance.
- NMA – includes all PHO's in Australia except Northern Territory and Tasmania.
- SWSLHD HREC can also approve for private sites (i.e. SWSPHN, private hospitals, etc). However, in order to do this, the private site needs to accept SWSLHD HREC as the lead Ethics of the project by signing an External Entity Agreement (EEA) which is required under NSW Health Policy. Standard agreement.
- If any of the proposed sites are universities, SWSLHD HREC cannot provide ethical review. However, most universities will ratify SWSLHD HREC approval. Please speak to the relevant university for more information.
- EEA involves a fee of \$150 inc. GST payable by the private site.



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# If no SSA generated after Project Registration submission

In order to generate NSW Public Health sites for this application, please follow the below steps:

- Click on the 3 dot menu next to the ETH identifier and click on 'New version'
- Now that the status of the application is 'In Progress' you will be able to click on the '+New Site' button above the list of ETH and STE identifiers.
- Follow the prompts and fill out the details for the site e.g. PI details, site details etc.

Same process if it is an NMA study.



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# Edit Access

CPI will be able to give application access to team members to draft the HREA and SSA forms. NOTE: CPI and PI must submit the final forms in replacement of physical signatures.

Select the 'Options' icon to the left of the Ethics/Site Application you wish to share access.

Select



Invite user to register or share project

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



Invite user to register or share

Manage access

The list of users currently assigned to the application are listed.

Access

Select the drop down list to increase or decrease the access of those listed.



Delete access by selecting this icon.



Resend an invitation to register by selecting this icon.

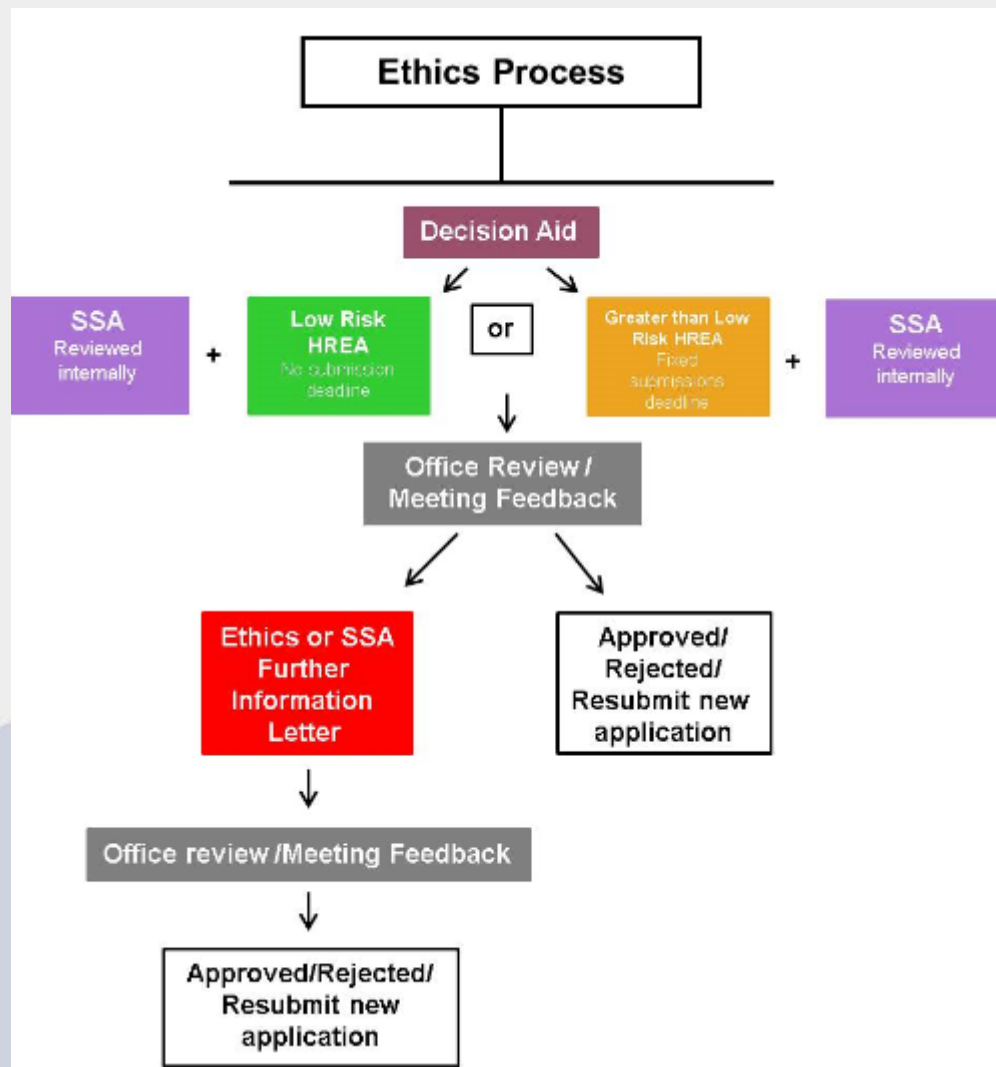


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# Human Research Ethics Application (HREA)



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# Greater than Low Risk Application HREC MEETING DATES FOR 2020

Please refer to our website for yearly updates

Submission Closing Dates	HREC Meeting Dates
Friday, 31 January 2020	Monday, 17 February 2020
Friday, 28 February 2020	Monday, 16 March 2020
Friday, 3 April 2020	Monday, 20 April 2020
Friday, 1 May 2020	Monday, 18 May 2020
Friday, 29 May 2020	Monday, 15 June 2020
Friday, 3 July 2020	Monday, 20 July 2020
Friday, 31 July 2020	Monday, 17 August 2020
Friday, 4 September 2020	Monday, 21 September 2020
Friday, 2 October 2020	Monday, 19 October 2020
Friday, 30 October 2020	Monday, 16 November 2020
Friday, 27 November 2020	Monday, 14 December 2020



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# Decision Aids

Should I check with the Research Directorate before completing an ethics application?

YES!

## Decision Aid:

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



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# ETHICS – Status Flowchart

1. **Submitted** when you submit the HREA.
2. **Eligible / Ineligible** after administration checks are done.
3. If **ineligible**, follow [QRG – Ineligible Notification – Resubmitting Application](#). The HREA will then go back to **submitted**.
4. **Under Review/Assigned to meeting** when the HREA is with the Ethics Committee for review.
5. If further clarification is needed, HREA will be **Information Requested** . Please note that we require a response cover letter and updated documents in tracked and clean.
6. 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.
7. If the application is ready for approval as deemed by the Ethics Committee, the HREA will be **Approved**. You will receive an approval email via REGIS.



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# Example of an Ethics Application

 Logged in [Josh Yip]

Research Ethics Governance Information System

Applications (2017/PID01524) | Projects | Project Details (2017/PID01526) | Applications (2017/PID01526) | Edit Application

## 2017/ETH00987 - Test Project 2 08122017 - HREA

☒ Introduction

☒ Project Overview

☒ Project Team

Project Team Details

(1) Mr Josh Yip

☒ Disclosure of Interests

☒ Restrictions

☒ Evaluations

☒ Location

☒ Methods

☒ Participants

☒ Method Specific

**Interventional/Clinical Trials research**

Participant Specific

Project Details

Recruitment

Consent














































Risk

### Interventional/Clinical Trials research

General | Clinical Trial Drugs | Clinical Trial

**M6.1 Briefly describe the intervention/s that you will be using.\***

- You should describe the types of interventions (e.g. substances, devices, treatments, therapies, new models of care, techniques or processes) and the contexts in which they will be used.

**B** *I* U ~~S~~                                             

**M6.2 Is your intervention related to the prevention, diagnosis, treatment or management of a health condition? \***

☒ Yes ☐ No

**M6.2.1 Do you consider that you are conducting a clinical trial? \***

- The World Health Organization defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes".
- Interventional research that is not health-related may use trial methodology, e.g. randomisation, but it is not a 'clinical' trial.

☒ Yes ☐ No

**M6.2.1.1 What does the clinical trial involve the use of? \***

- "Other" may include, but not be limited to, surgery, radiation and diagnostic test. It may also include non-physical interventions being investigated in a clinical context.

## Application submission

The application **2017/ETH00985** has been successfully generated.

Your application has been successfully submitted. Thank you for your application. To continue please click the close button.

< Back

✕ Close

You can still download PDF of the HREA / SSA and study documents if you want to.

The process will be the same for SSA.

## Application submission

Select the application attachments you wish to download:

All application forms and attachments (.zip)

*This package of files contains your application content, attachments, and other files supporting your application.*

> Next



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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.
- Research in which the risk for participants is more serious than discomfort is not low risk.
- 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.
- Requirements for the ethical review of low risk research and negligible risk research are set out in the National Statement.



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# Low risk research

Examples of low risk research – Low risk HREA pathway include:

- Retrospective audit
- Secondary use of data for a research purpose
- Low Risk Surveys and Focus Groups



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# 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



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# Greater than low risk research – Research Method

- Action research
- Biospecimen analysis research
- Data linkage research
- Ethnographic research
- Epidemiological research
- Interventional/Clinical Trials research
- Observational research
- Survey/Interview/Focus Group research
- Textual analysis research



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# Greater than low risk research

Examples of greater than low risk research – Greater than low risk HREA pathway 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





# Protocol Tips

Please note that a substantial Protocol is required to be submitted for review. The Research Directorate strongly recommends using the Protocol Template available on the SWSLHD Ethics website, which has been endorsed by the SWSLHD HREC:

<https://www.swslhd.health.nsw.gov.au/ethics/forms.html>

Please ensure the protocol has the following information:

- A footer that lists the name of the document, version number and date.
- The rationale/background must have references
- Check for a request for waiver of consent if required
- Ensure that Ethical Considerations are listed in the Protocol (see section 7.1 of the Protocol Template)
- Ensure that data collection items are listed in the protocol



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# MASTER documentation

The Participant Information Sheet/Consent form/Flyer/Brochure refer/s 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 2018*



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# ETHICS - Tips

- Please ensure that you do NOT copy your application unless you have received an 'Not Approved' email/status.
- Please ensure that all documents submitted to the office for HREC review have version control e.g. Document title, version number and date.
- Please ensure that a Western Australia or Victorian Specific Module has been uploaded and submitted for sites that involve VIC/WA.
- The Coordinating Principal Investigator (CPI) will be able to give application access to team members to draft the HREA and SSA forms. **NOTE:** The CPI and Principal Investigator (PI) must submit the final applications in replacement of physical signatures in REGIS.
- All NSW/ACT sites where the research will be conducted are required to be listed in the **Project Registration** . If the sites are not selected at the time of registration, the SSA will not generate and the sites will no be added until ethics approval, via an amendment submission.
- Please ensure a **Protocol** based on the SWSLHD template: [Protocol Template](#) is uploaded with the ETH application in REGIS.  
**NOTE:** *Applications will not be considered without a Protocol.*



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# Common issues, mistakes and omissions

- Contact the Research Office before submitting your application – we are happy to pre-review your draft protocol via email, and meet if necessary.
- Review your attachments to ensure there are no grammatical and spelling errors, etc.
- Ensure all documentation have title of document, version number and date.
- Don't forget to complete your SSA after your HREA.

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

**1.9.10** MUST be Coordinating Principal Investigator.

**1.9.11** MUST have Yes selected

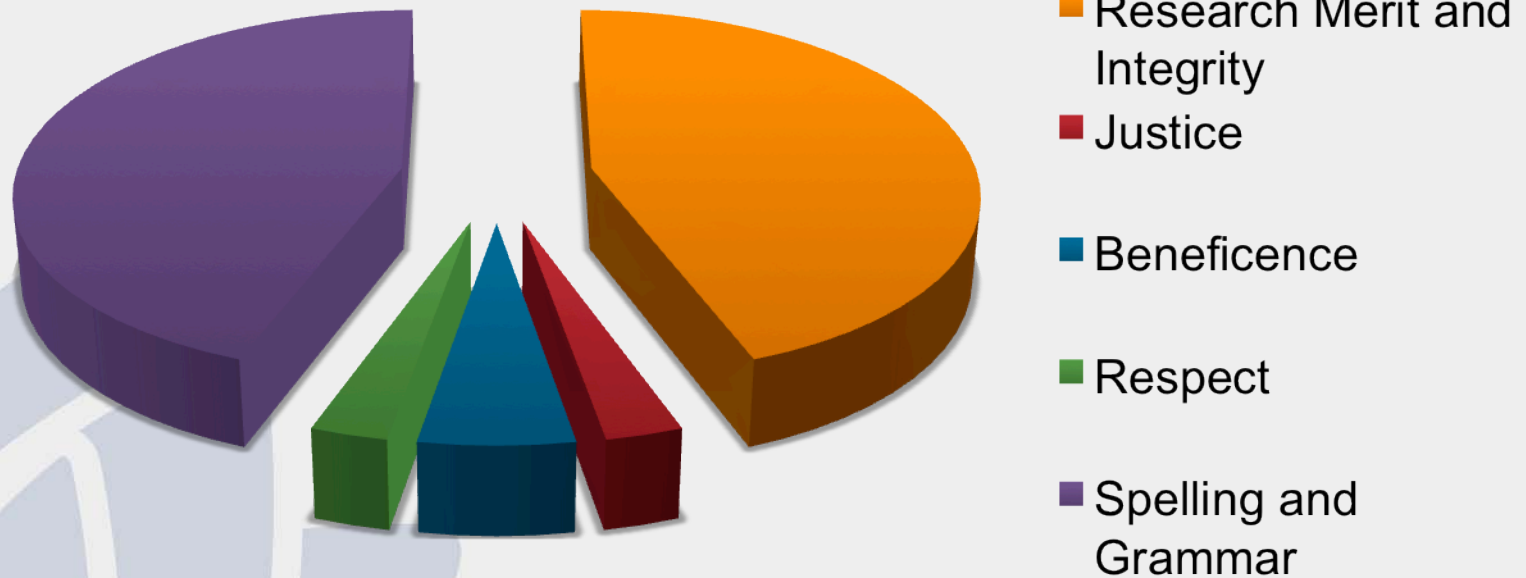


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# Ethical Issues in the SWSLHD

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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](mailto: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](mailto:support@f1solutions.com.au)

Website: <https://regis.health.nsw.gov.au/>

Phone: 1300 073 447



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# Questions



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