# Conducting Research at SWSLHD



#### **Administration Officer**

**Research Directorate** 



### 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









#### 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



#### 2023 Rollout of OHMR Metrics strategy SWSLHD – Metrics Performance



Target (red line) – 75%

Average time lapsed

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Office for Health and Medical Research – March 2022 GOVERNMENT Metrics Activity Report for NSW PHOs - 01/07/2021 – 30/09/2021

#### 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





### **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



# **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 <u>Decision Aid form</u>



- ✓ Email the Decision Aid to <u>SWSLHD-</u>
   <u>Ethics@health.nsw.gov.au</u> 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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# Low risk research

#### Low risk and negligible risk research

- The expression 'low risk research' describes research in which <u>the</u> 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





# 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)





Google

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

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 dep't 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 (ORGs)



OUICK REFERENCE GUIDES

Follow useful advice on preparing assessing and

REGIS





**HELP DESK & FAOS** 

Get help desk support or refer to FAOs for approving ethics and site governance applications in Researchers and Applicants to have your questions

answered



**REGIS TRANSITION - COMPLETED APRIL 2019** 

ACT and NSW public health organisations have introduced REGIS for ethics and site-governance

**Q** REGIS

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### **Creating a New Project**

🕮 Create a form	
+ New form Project Registration	
♥ Top 5 milestones due	
O There are no records to display.	
E Your activities	
Projects	
Click Project in top right Registration.	corner, then New Form, then Project
You will need to register automatically generate the	your project first, then REGIS will ne required HREA and SSA(s).
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GOVERNMENT

#### **Creating a New Project**



### 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	6							
Project Title								
Title Free Text Part]								
roject Summary								
[Title Free Text Pa	t]							
Study type: <mark>[e.g.  </mark>	lealth Research/ Social Scien	ce]						
ls application beir	ng submitted under NMA: <mark>Ye</mark>	es/No						
Has the project ev submitted to an N	ver received ethics approval HMRC registered HREC, for	, or has an ethics application form ever been r the project? <mark>Yes/No</mark>						
Sponsor								
Sponsor type: <mark>[Tit</mark>	le Free Text Part]							
Sponsor name: <mark>[S</mark>	outh Western Sydney Local F	lealth District]						
Coordinating	Principal Investigator							
CPI Name	[Full Name]							
ORCID	[If Applicable]							
Sites								
NSW Site		Principal Investigator						
South Western Syc (Site)	Iney Local Health District	[PI Name]						
ACT Site		Principal Investigator						
Other Site		Principal Investigator						
HREC								
HREC Name: [ <mark>Sou</mark>	th Western Sydney Local Hea	alth 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





#### Example of selecting a site

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.

Líverpool Ho	spital		South Western Sydney Local Health District	
ACT Health	N <i>S</i> W Health	Other health jurisdictions or organ	ations	
Nominat A researc A 'Centra Specific A A Princip when a p who has t If you are process.	e the project site/s w th project may be co a may be a Local Hea Assessment (SSA) will bal Investigator (PI) is roject does not requ the authority to subr a unsure of the name	ithin NSW Health and a Principal Im nducted at one or more sites within o Ith District (LHD), a Specialty Health I be generated for each site nominate is the person responsible either indivi- ire the appointment of a NSW Health nit the Site application. An incorrect s of the Centre or Site/s your project	tigator for each site or more Centres within NSW Health. atwork, a Pillar organisation, an affiliated health organisation or other health organi ally or as a leader of the researchers at a site, for the conduct of research at that site incipal investigator, the coordinating principal investigator may also be the princip ponse here may cause the application to be Ineligible and will cause delay in proces I be conducted at, please discuss with your local research office. An incorrect selec	sation operated by NSW Health. A Site In a single site research project or al investigator. The PI is the only person sing. tion here can delay your application
📑 Pro	oject Centre *		Project Site *	
Se	outh Western Sydney	/ Local Health District 🔹 🗸	Liverpool Hospital	~
Prí	ncipal Investigator e	mail (REGIS username) * 🝘		Prínciple Investigator name
Lo	gan.Lown@health.ns	sw.gov.au		Logan Lown
$\oplus \ominus$	<b></b>			





#### 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.





#### **Project Registration**

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Y	$\mathbf{\Theta}$	$\odot$

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

Part B: Project Details

Introduction

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** 

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



### 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'

Applications Details

Project details are on this page.

#### New Site

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

				\$ 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
				1

Same process if it is an NMA study.



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#### **Edit Access**

TITLE			STATUS
053058 - Project Registration			In Progress
Invite user to register or share form	ldentifier 053058	Owner	
Delete form	Title Project Registration		
	Status In Progress		
	Related identifier		

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

😁 Invite user to register or share



🚰 Manage access

application are listed.

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The list of users currently assigned to the

listed

icon.

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Delete access by

selecting this icon.

Resend an invitation to

register by selecting this

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

#### Terms in REGIS

Project Reference # = 2023/PIDXXXX Ethics Reference # = 2023/ETHXXXX Site Specific Reference # = 2023/STEXXXXX Application = Pre approval documents Project = Post approval documents

Application





# Human Research Ethics Application (HREA)



### 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 <u>should not</u> 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



### **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 <u>QRG Ineligible Notification Resubmitting Application</u>. 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





### Submitting an SSA Application

La Export CSV Show 10  v entries Search:						ch:		
		Identifier	\$ Títle	Comments	Version	Status	\$ Owner	Created date
►	:	📽 <u>2019/ETH12546</u>	SWSLHD Zip Test		0.00	Submitted	Logan Lown	12/12/2019 03:48:00 PM
F	:	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	Malína Peng	12/12/2019 03:51:10 PM
Show	ing 1 t	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



#### 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**

Part B: Site Team 🛛 🗸 🗸	
Part C: Departments and Services	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.
Part D: Recruítment, Records, Tíssue and Data	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.
Part E: Site Costing and Funding	If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.
Part F: Attachments – Síte Specífic Documents	E C1. Department *
Part G: Declaration	✓
	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: * 📀
	$\oplus \bigcirc \oslash$

Part C: Departments and Services	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 formation in this section. Each Head will be notified by email of the need for them to respond to the support request you submit.							
Part D: Recruítment, Records, Tíssue and Data	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 or 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 activitie others may require in-kind support.							
Part E: Site Costing and Funding	If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.							
Part F: Attachments - Site Specific Documents	C1. Department *							
Part G: Declaration	LIV - Clinical Information/Medical Records							
	C2. Department Head Name Ashna Sharma							



#### **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

	TITLE		COMMENTS		VERSION		STATUS	
📽 2021/STE02997	A Multi-centre	Re			1.00		Completed	l pen
Application information		Identifier						
Invite user to register or share application		202 Title	1/STE02997	Com	pleted pending			

Application Details Decisions Forms Applications

Application details are on this page.

Export CSV Search						
TITLE	т	APPROVAL		T CREATED DATE	Ŧ	OUTCOME
Head of Department Support for Site Specific Ass	essment	Bankstown Lidcombe Hospital		23/07/2021		Pending
	Decisions					
	USER DECISION COMMENT	OVERRIDDEN OVERRIDDEN DECISION	ASSIGNED DATE			
	SM		23/07/2021			
				<b>NSW</b> GOVERNMENT	<b>Health</b> South Western Sydney Local Health District	

### 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 <u>QRG Resubmit a new version of the application after an</u> <u>ineligible notification</u>. 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.





#### **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/STEXXXX).
  - 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



#### 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







