



# REGU/REGIS Newsletter | Issue 18 | 18 September 2024

## In this issue

- **National One Stop Shop**
  - **Research Office Action**
  - **REGIS/National One Stop Shop Survey Responses - Thank you for the great responses**
- **Professional Highlights - Research Administrator Appreciation Day**
- **REGIS Serious Breach Notification Workflow Update**
- **Previous Versions of REGU/REGIS Newsletter**

## National One Stop Shop Discovery Workshops

Discovery Workshops

**Audience:** Research Office

<b>NSLHD Submission Checklist - Research Governance - Site Specific Assessment (SSA) For a Greater than Low Risk Research Application</b>	
<ol style="list-style-type: none"> <li>1. The SSA form must be completed within <a href="#">REGIS</a>.</li> <li>2. All site specific applications must comply with the below checklist – failure to do so may result in an ineligible application.</li> <li>3. All additional documents to be uploaded in REGIS. Please refer to the <a href="#">Quick Reference Guides</a> (Project Registration, Site Specific Application - Completing &amp; Submitting, National Mutual Acceptance (NMA) in REGIS).</li> <li>4. Please <a href="#">contact</a> the Research Office if you have questions about your research project or application in REGIS, for any technical support, call REGIS Help Desk on 1300 073 447.</li> </ol>	
Section 1: SSA Application and Supporting Study Documentation	
<input type="checkbox"/>	<b>Cover Letter</b> – addressed to the Research Governance Officer (RGO) which lists all documents being submitted including versions and dates, indicates if the application is a student project, addresses any application specific items that you wish to bring to the attention of the RGO, and gives an explanation on why any items listed on the Submission Checklist have not been provided. The cover letter must be signed by the Principal Investigator. <a href="#">Click here to view a sample cover letter</a> .
<input type="checkbox"/>	<b>Method of Payment (MoP) Form</b> Applications will not be processed without completed Method of Payment Form.
<input type="checkbox"/>	<b>SSA Form</b>
<input type="checkbox"/>	<b>Relevant Departmental Approval/s</b> – Appropriate head of department support & declaration. If the department you are conducting research in is not listed on REGIS, please contact NSLHD Research Office on 02 9926 4590 and advise us of the department name and head of department contact person.
<input type="checkbox"/>	<b>Site Specific Participant Information Sheet(s) and Consent Form(s) (PISCF) including version number and version dates</b> - This is a copy of the Master Participant Information Sheet and Consent Form which includes information pertaining to the site at which the research is to be conducted, e.g. local contact details, (e.g. <b>Name:</b> Research Governance Officer, <b>Email:</b> <a href="mailto:NSLHD.Research@health.nsw.gov.au">NSLHD.Research@health.nsw.gov.au</a> , <b>Phone Number:</b> 02 9926 4590, <b>NSLHD Reference:</b> 20XX/STEXXXXX), local investigators and <a href="#">local logos</a> on documentation.
<b>For projects where the ethics application has been approved outside of REGIS (prior to REGIS implementation or by an HREC outside of NSW and ACT, please also upload the following:</b>	
<input type="checkbox"/>	<b>HREA</b> - A copy of the Research application form approved by the HREC.
<input type="checkbox"/>	<b>Ethics Approval Letter</b> - The Ethics Approval Letter from a Lead NSW Health Human Research Ethics Committee (HREC) and any subsequent amendment approval letters (for multi-centre LNR Projects. <i>*The letter/s must list each of the sites at which the study will be undertaken.</i>
<input type="checkbox"/>	<b>HREC Approved Master Participant Information Sheet(s) and Consent Form(s) including version number and version dates</b>
<input type="checkbox"/>	<b>HREC Approved study documentation: protocol, questionnaire(s), survey questions, patient diaries, recruitment advert, interview topics to be covered etc. including version number and date (if applicable)</b> All documents intended for use at a NSLHD site must be submitted with evidence of ethics approval. <i>Please note any documents that will be received and/or viewed by a participant/patient must be made into a site specific format.</i>

Members of the Office for Health and Medical Research have been attending initial discovery workshops with the National One Stop Shop project team. We joined other jurisdictions in describing the "current state" of ethics and governance.

We have come away with some homework. The NOSS project team is looking to build an understanding of what a valid application would be. Could research offices please send through a copy of your [Ethics and Site application checklists](#).

## REGIS/NOSS Survey Responses

### Audience: All

Last newsletter we sent out a request for you to complete some surveys regarding your use and barriers in using REGIS. We would use these responses to help us prepare for an upcoming meeting with the NOSS team in early October. Then two days later we received notification of discovery workshops that would start THIS WEEK! We put the call out and asked for you to respond ASAP, and you did not disappoint.

We have received over 400 individual responses across the surveys sent out. We were thrilled to receive so many well thought out and constructive comments that are helping us build picture of what is working in our current system, what you want in a future national system and even some things we can focus on in the short term to make your experience better.

Thank you to those who put their hands up to be contacted again and continue on this National One Stop Shop journey with us. Please know when we know more, we will share it with you all.

---

*The challenge is finding the right balance....*

---

### What the Research Offices Responded

[More Details](#)

Support Tool	12
Minimum Dataset Form	7
I Don't think Project Registratio...	3
Other	3



### What the Researchers Responded

[More Details](#)

Support Tool	37
Minimum Dataset Form	53
I Don't think Project Registratio...	19
Other	15



One of the interesting, but perhaps not completely unexpected, themes to be coming up is that depending on your role in the submission and management of human research applications your expectations of how a system should work are.....very different.

Take this example where we asked the exact same question of our Research Offices and Researchers.

**"In your opinion, should a project registration be a minimum data set form (less questions) OR a researcher support tool that helps researchers identify critical decision points such as if a study is a clinical trial or clinical research"**

Research Offices sit majority in the support tool camp where Researchers are currently sitting in the minimum dataset camp.

Something to ponder on while we navigate National One Stop Shop together.

# Celebrating our Research Administration Professionals

**Audience:** All

---

*[NSW Medical Research](#) is proud to be sponsoring a range of activities over September to celebrate the important work of our Research Administration Professionals.*

---

In the lead up to Research Administrator Appreciation Day on September 25 the Office for Health and Medical Research is highlighting some of the amazing Research Administration Professionals across NSW Health.

**Kellie Hansen** the Manager of the Research Office at Western Sydney Local Health District, who recently celebrated 8 years in the role, was first off the rank.

If you haven't seen it already, check out Kellie's [professional highlight published on LinkedIn](#) last Wednesday. Make sure you like and repost.

---

*Keep your eyes out for the other Professional Highlights over September*

---

- **Lucia Smith** - Research Governance Manager - SCHN - Monday 16 September
- **Vidura Perera** - Research Ethics and Governance Officer - NSLHD - Thursday 19 September
- **Barbara Taylor** - Director Research - MLHD - Wednesday 25 September





**Research Administrator  
Appreciation Day  
25 September 2024**

*Celebrating our Research Administration  
Professionals*

*Professional Highlight*



NSW Health Research  
Administrator Awards  
*Celebrating our Research  
Administration Professionals*



*Lucia Smith, Research Governance  
Manager, Sydney Children's Hospital  
Network*



**Research Administrator  
Appreciation Day  
25 September 2024**

*Celebrating our Research Administration  
Professionals*

*Professional Highlight*



NSW Health Research  
Administrator Awards  
*Celebrating our Research  
Administration Professionals*



*Vidura Perera, Ethics and Governance  
Officer, Northern Sydney Local Health  
District*



**Research Administrator  
Appreciation Day  
25 September 2024**

*Celebrating our Research Administration  
Professionals*

*Professional Highlight*



NSW Health Research  
Administrator Awards  
*Celebrating our Research  
Administration Professionals*

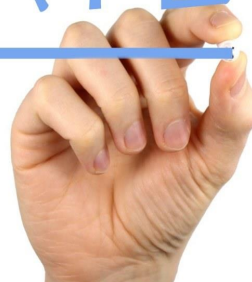


*Barbara Taylor, Director Research,  
Murrumbidgee Local  
Health District*

## REGIS Serious Breach Notification Workflow Update

**Audience:** Research Office/Researchers

# UPDATE



The eHealth REGIS team have made minor changes to the Serious Breach Notification workflow, these changes mean that upon submission of this safety form, an automatic submission acknowledgement email is sent to the Coordinating Principal Investigator (CPI), related Principal Investigators (PI) and Administration contacts.

This change will be live from Thursday 19 September 2024.

## Upcoming events and dates

**Audience:** Research Office/Researcher



### 2024 Events and Dates

**REGIS Research Office Lunch & Learn 2024:** Future sessions to be scheduled. [Click here to view the themes, topics and previous Lunch & Learns.](#)

**Research Office REGIS Training:** Research Office training for 2024 is complete! Training dates for 2025 will be released later in the year.

**Researcher REGIS Training:** Researcher training for 2024 is complete! Training dates for 2025 will be released later in the year.

## Previous Versions of REGU/REGIS Newsletter

**Audience:** Research Office/Researcher

All previous version of the fortnightly email are available from the REGIS website: <https://regis.health.nsw.gov.au/news-and-events/regis-office-webinars/>

*REGU/REGIS Newsletter: Inspiring other units within OHMR and LHDs since February 2021*