

Research Governance Submission Guidelines Site Specific Applications via REGIS

These guidelines are intended to assist with a Site Specific Application (SSA) for review via REGIS by the Sydney Children's Hospital Network (SCHN) Research Governance.

SCHN Research Governance Office (SCHN RGO) is responsible for the review of all types of SSAs associated with a Human Research project that may be conducted at any of the six (6) sites within SCHN.

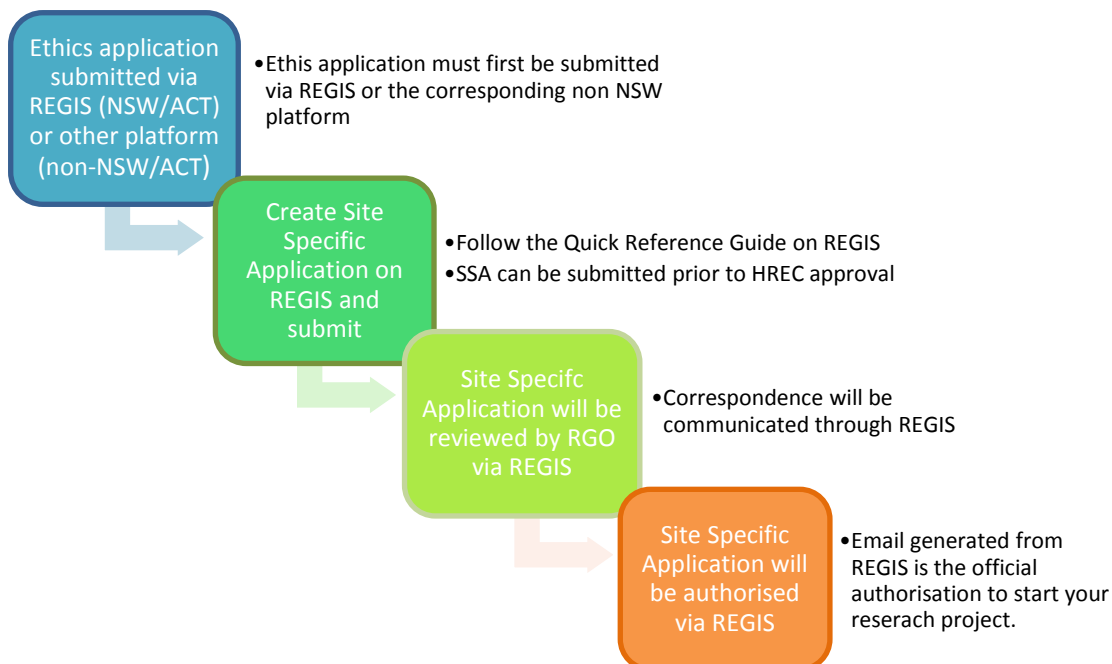
These sites are:

1. The Children's Hospital at Westmead (CHW)
2. Sydney Children's Hospital, Randwick (SCH)
3. Newborn Emergency Transport Service (NETS)
4. Bear Cottage
5. The Children's Court Clinic
6. NSW Pregnancy and Newborn Services Network (PSN)

SCHN RGO encourages the submission of a single SSA for multiple sites across SCHN; however, separate SSAs for each site can be submitted at the investigator's discretion or recommendation by SCHN RGO.

For further advice or information, please contact SCHN Research Governance via email at SCHN-Governance@health.nsw.gov.au or via telephone on 02 9845 3011.

Overview



REGIS Implementation at SCHN Research Governance

Please refer to the following timeline for transition to REGIS at SCHN:

From 29 October 2018:

- Local ethics applications submitted to SCHN HREC via REGIS must submit Site Specific Application via REGIS.
- All other ethics applications including Multi-Centre and Clinical Trials submitted to any HREC continue to submit Site Specific Application via Online Forms.

From 1 December 2018:

- Ethics applications submitted to any NSW HREC via REGIS must submit Site Specific Application via REGIS
- Ethics applications submitted to any NSW HREC via Online Forms continue to submit Site Specific Application via Online Forms
- Ethics applications submitted to a HREC not in NSW must submit Site Specific Application via REGIS.

Important Information

- While another member of the study team may prepare the SSA, the Principal Investigator is the only person who can submit the SSA in REGIS.
- The SSA can be shared to view or edit. Review the QRG 'Completing Site Specific Assessment' <https://regis.health.nsw.gov.au/how-to/>
- There are no submission closing dates for Site Specific Applications.
- The Research Governance checklist is a mandatory document that will be required to be uploaded in Part F of the REGIS SSA. There are two checklists:
 1. Research Governance Submission Checklist REGIS using a **NSW/ACT HREC**
 2. Research Governance Submission Checklist REGIS using a **non-NSW/ACT HREC**Please ensure you are completing the correct checklist.
- Please use the following naming convention of uploaded files:
Type of document – version number – dated (DD/MMM/YYYY)
Examples:
Parent Guardian ISCF – CHW V1 – 23 May 2018
Child Information Sheet – SCH V2 – 15 Aug 2018
- If you have submitted your SSA and forgotten to upload an attachment contact the Research Governance Office for assistance.
- Please refer to the SCHN Consenting SOP and SCHN Branding Guidelines in creating Site-specific Documents (hyperlink SOP and Branding)
- Access Request applications will not be submitted on REGIS. Please contact Research Governance for further information.

- Amendments post site authorisation will continue to be processed as per existing procedures on the [Research Governance Amendment form](#) with relevant documentation emailed to SCHN-Governance@health.nsw.gov.au
- Meet the team:

Dr Lucia Smith	Research Governance Manager
Dr Geraldine Bicol	Research Governance Officer
Dr Amelia Assareh	Research Governance Officer
Jessa Morales	Research Governance Officer
Meera Heidary	Research Governance Support Officer
Abhi Satya	REGIS Research Governance Support Officer

Before Getting Started

1. To complete a site specific application you must first have a REGIS account. To create an account, the REGIS website can be found here: <https://regis.health.nsw.gov.au/>
2. All persons who will be involved with the study must have a REGIS account. If they do not have an account before you start the site application there will be opportunity to invite them to join REGIS during the preparation of the site application.
3. Please ensure you have had prior discussions with the principal investigator's Head of Department and any Heads of supporting departments about requesting their support for your study. Declarations of Support will be made online via REGIS.
4. If your study has (or you suspect it may require) an agreement (e.g. a standard Medicines Australia Clinical Trial Research Agreement (CTRA), a Research Collaboration or Service Agreement, a Material or Data Transfer Agreement,) it will require discussion with Research Governance prior to site application in REGIS. If your study is submitted with an agreement and it has not been discussed with Research Governance, your application will be rejected.
5. If you are conducting a clinical trial and would like SCHN to be the sponsor and so submit the Clinical Trial Notification (CTN) to the Therapeutic Goods Association (TGA) please contact Research Governance prior to submitting your SSA for discussion.
6. If you will be recruiting patients between the ages of 16 – 18 years or during the course of your study participants will turn 18 years or older please contact Research Governance prior to submitting your SSA for discussion to ensure compliance with SCHN Age of Admission policy.
7. Any researcher, including University students who will: (1) conduct the study on site; (2) access patients' identifiable information; (3) have face to face contact with patients, families and SCHN staff are required to provide the following:
 - a. Email from Workforce confirming Workforce Clearance. Workforce can be contacted through the hospital switchboard 02 9845 0000
 - b. University or Employer's Professional Indemnity Insurance
 - c. University or Employer's Public Liability Insurance (for researchers conducting the study on site)

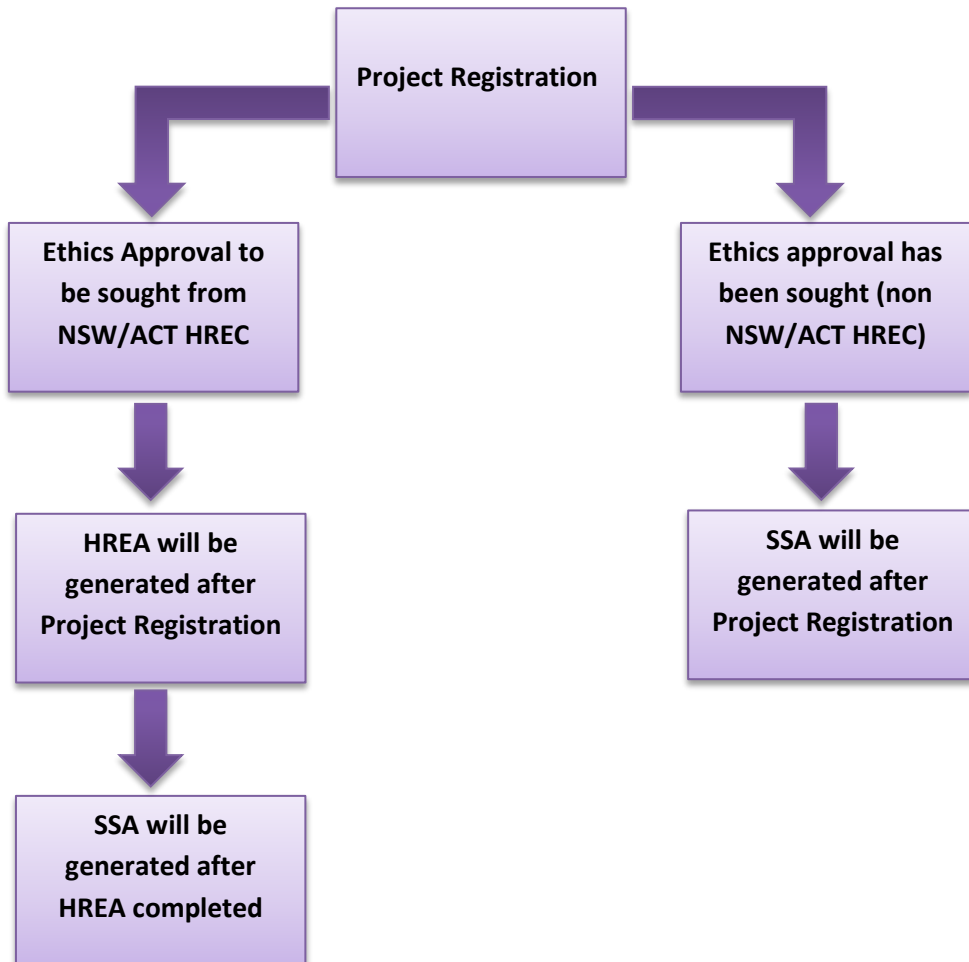
- d. Additional which may be requested: confirmation email from the University or Employer that the involvement of the researcher on the study is covered by the University's or Employer's Insurance
 - e. NB: USYD and UNSW - evidence of insurance has been provided by these Universities to the Research Governance Office, however evidence that the project forms part of the student's coursework must be provided. This evidence may be in the form of the University supervisor sign off or University HREC approval if applicable.
8. Ensure you have all the mandatory documents on the Research Governance Submission Checklist. The checklist can be found on the Research Governance [intranet](#)/[internet](#) pages.
9. You will need to have this ready to be uploaded into REGIS as an attachment in Part F.
10. RELEVANT CONTACT LIST:
- SCHN Research Governance Office:
 - Phone: (02) 9845 3011
 - Email: SCHN-Governance@health.nsw.gov.au
 - SCHN Workforce:
 - Phone: (02) 9845 3547
 - Email: schn-recruitment@health.nsw.gov.au
 - Health Information (Medical Records) Unit Managers (Data Provision Managers-Declaration D):
 - Nadine.Ghassibe@health.nsw.gov.au (SCHN Network Manager)
 - Martina.Watson@health.nsw.gov.au (SCH HIU Manager)

Completing a site specific application in REGIS

Each site specific application is linked to a Project. If your study is approved by a non-NSW/ACT HREC you must still create a Project in REGIS first before a site specific application can be generated. If you have put your ethics application through a NSW/ACT HREC then the Project Registration should have already been completed before completing the Ethics Application.

Please follow the Quick Reference Guides (QRGs) on the REGIS website to assist you in completing a site specific application on REGIS: <https://regis.health.nsw.gov.au/how-to/> "Completing a Site Specific Application".

The below flow-chart outlines the process required to submit your SSA via REGIS



Associated Links

- Research Ethics and Governance Information System (REGIS)
<https://regis.health.nsw.gov.au/>
- Research Governance in NSW Public Health Organisations
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2011_001
- Fees For The Review of Ethics and Site Specific Assessment Applications
<http://webapps.schn.health.nsw.gov.au/epolicy/policy/3147>
- Delegations Manual- SCHN Policy - Section 14
<http://webapps.schn.health.nsw.gov.au/epolicy/policy/3965>
- Directorate of Clinical Operations and Department Heads
<http://intranet.schn.health.nsw.gov.au/files/attachments/4559/2018.schn-directorate-clinical-operations.pdf>
- Clinical Trials regulation in Australia
<http://www.tga.gov.au/clinical-trials>
- Clinical Trial Research Agreements for Use in NSW Public Health Organisations
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2011_028
- Clinical Trials - Insurance and Indemnity - NSW Health Policy Directive
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2011_006
- Age of Admission Policy
<http://webapps.schn.health.nsw.gov.au/epolicy/browse/alphabetical>