

SWSLHD REGIS Training

Tips and Tricks

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Research Directorate



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New Terms in REGIS

Application = Pre approval

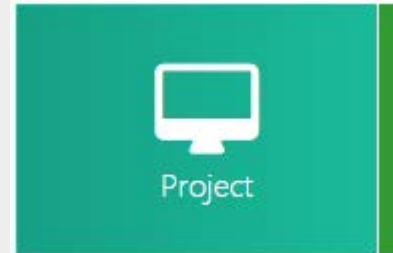
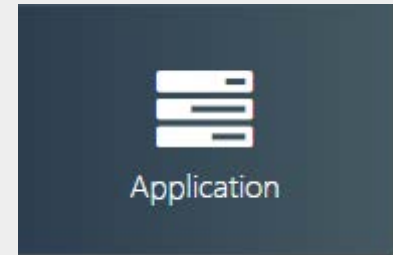
Project = Post approval

Project Reference # = 2019/PIDXXXXX

Ethics Reference # = 2019/ETHXXXXX

Site Specific Reference # = 2019/STEXXXXX

Submit Project Registration to get access to new Ethics and SSA including NMA.



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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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NMA QRG – if HREC is outside NSW

Please complete [National Mutual Acceptance \(NMA\)](#) in REGIS for when another state is the lead HREC for the study, therefore already received ethics approval.

IMPORTANT: Make sure you upload all supporting documents such as ethics application, HREC approval letter, amendment approvals, MASTER documents and any other supporting documents.

Please note that Northern Territory and Tasmania are not part of NMA. Please contact their Ethics offices directly for further information.



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National Mutual Acceptance (NMA) in REGIS

Part A: Previous Ethics Application



If an ethics application:

Has never been previously submitted for this project to a NHMRC registered and/or certified HREC, select 'No' at question A1 - no further questions will be required in this section and you can proceed to Part B.

Has previously had an ethics application submitted to a NHMRC registered and/or certified HREC, select 'yes' at question A1 and complete the additional questions displayed.

A1 Has an application for ethics review of this project previously been submitted to a recognised HREC? *

☒ Yes ☐ No

The following details are required to identify the previous ethics application, the HREC to which it was submitted and whether it was submitted under the NMA arrangements which exist between a number of public health jurisdictions nationally. Outcomes or status of that previous application may be requested.

A2 Ethics application ID *

A3 HREC Name *

A4 HREC Code

A5 Was/Is application being reviewed under the NMA scheme *

A6 Outcome or status *

☐ Approved
☐ Not approved
☐ Review currently underway



NSW Sites (Project Registration, Part c Research sites)
will have SSA generated after Project Registration



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Decision Aid

Aim: to assist researchers in choosing the correct ethics pathway or if it is classified as QA/QI (ethics approval not required).

Strongly recommended.

This document is found on our Research Directorate website under forms and templates. Please email over to our office for review.



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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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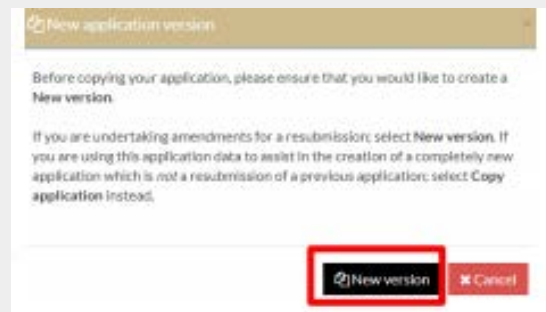
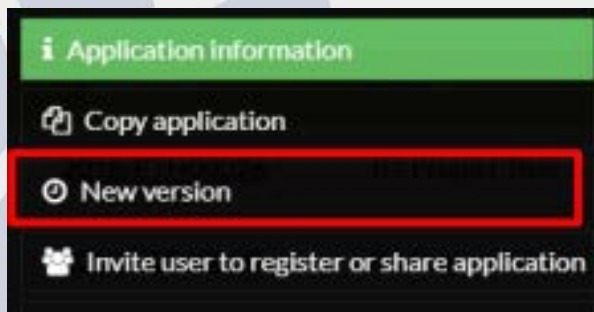
SSA – Status Flow Chart

1. **In Progress** – site specific application being completed/drafted.
2. **Completed Pending HOD** - awaiting support from the HOD in REGIS
3. **Pending Submission** – awaiting for the CPI to submit in REGIS
4. **Submitted** - submitted the SSA to the Research Directorate
5. **Eligible / Ineligible** after administration checks are done.
6. If **ineligible**, follow QRG – Ineligible Notification – Resubmitting Application. The HREA will then go back to **submitted**.
7. **Information Requested** – The Research Directorate has requested further information.
8. **In Progress** – Awaiting response from the CPI to the further information request sent
9. **Information Provided** – Further Information Request provided in REGIS – awaiting Research Directorate to review.
10. **Pending CE approval** – Awaiting for the CE/DOR to provide approval
11. **Authorised** – SSA authorisation email sent via REGIS



Responding to an ineligibility notification for Ethics + SSA:

1. Log into REGIS
2. Locate the application with the status of  **Ineligible**
3. Click on the 3 dots next to the application 
4. The application information menu will appear, please select “new version”. DO NOT **COPY**.

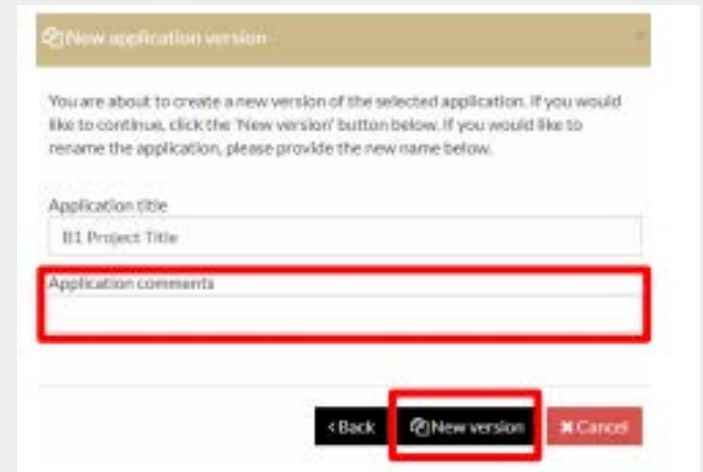


Responding to an ineligibility notification for Ethics + SSA:

5. A second message will appear. Unless you have been instructed, do not change the Application title. In the application comments cell, add a note to describe why you are submitting a new version, e.g. Resubmission after ineligible notification. Then click 'New version'.

6. The status of the application will have changed from “ineligible” to “in progress” which means you can now edit the form.

7. Click on the application: e.g. 2019/ETH0000 or 2019/STE0000 – an editable version of the form will now open – make changes required.



The screenshot shows a web form titled "New application version". Below the title, there is a paragraph of instructions: "You are about to create a new version of the selected application. If you would like to continue, click the 'New version' button below. If you would like to rename the application, please provide the new name below." The form contains two input fields: "Application title" with the text "B1. Project Title" and "Application comments". The "Application comments" field is highlighted with a red rectangular border. At the bottom of the form, there are three buttons: "< Back", "New version" (which is highlighted with a red rectangular border), and "Cancel".

changed from ● Ineligible to
● In Progress



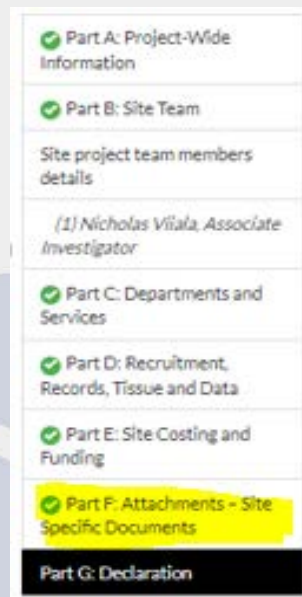
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Responding to a request for information – Ethics + SSA

Update add or remove documents: On the left-hand side menu of the form:

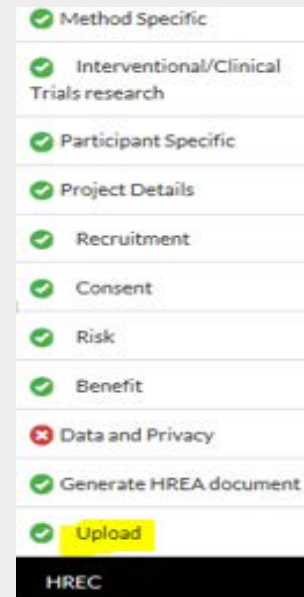
- HREA: Upload (ethics application)
- SSA: Part F Attachments – Sites Specific Documents (governance application)

SSA:



A screenshot of the left-hand side menu for the SSA form. The menu items are listed vertically, each preceded by a green checkmark icon. The items are: 'Part A: Project-Wide Information', 'Part B: Site Team', 'Site project team members details', '(1) Nicholas Vilala, Associate Investigator', 'Part C: Departments and Services', 'Part D: Recruitment, Records, Tissue and Data', 'Part E: Site Costing and Funding', 'Part F: Attachments - Site Specific Documents' (highlighted in yellow), and 'Part G: Declaration' (highlighted in black).

HREA:



A screenshot of the left-hand side menu for the HREA form. The menu items are listed vertically, each preceded by a green checkmark icon. The items are: 'Method Specific', 'Interventional/Clinical Trials research', 'Participant Specific', 'Project Details', 'Recruitment', 'Consent', 'Risk', 'Benefit', 'Data and Privacy' (preceded by a red X icon), 'Generate HREA document', and 'Upload' (highlighted in yellow). At the bottom of the menu is a black bar with the text 'HREC' in white.

Responding to a request for information – Ethics + SSA Notes for consideration:

- Response Letter/Cover letter: Create a response letter/cover letter that addresses all points raised in the request for further information and upload this for both SSA and Ethics responses.
- Please ensure that documents that have updates/changes are uploaded in both tracked and clean versions.
- Please ensure that version numbers and dates are updated in tracked and clean versions in the footer on each page of the document.
- If the application is not 'in progress' then click on the 3 dot menu and click 'new version'.



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Responding to a request for information – Ethics + SSA

Submit the application once you have completed all the changes to the application form and the documents, finalise the response by moving to the end of the form and using the left-hand menu. Click on HREA: Generate HREA Document (for ethics application) – or Part G Declaration then Complete SSA (for SSA application).

SSA:

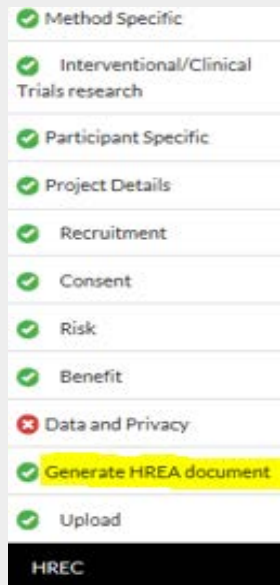


A screenshot of the left-hand menu for the SSA application form. The menu items are listed vertically, each with a green checkmark icon. The items are: Part A: Project-Wide Information, Part B: Site Team, Site project team members details, (1) Nicholas Vilala, Associate Investigator, Part C: Departments and Services, Part D: Recruitment, Records, Tissue and Data, Part E: Site Costing and Funding, Part F: Attachments – Site Specific Documents, and Part G: Declaration. The 'Part G: Declaration' item is highlighted with a black background and white text. Below the menu is a yellow button with the text 'Complete SSA'.

- ✓ Part A: Project-Wide Information
- ✓ Part B: Site Team
- Site project team members details
- (1) Nicholas Vilala, Associate Investigator
- ✓ Part C: Departments and Services
- ✓ Part D: Recruitment, Records, Tissue and Data
- ✓ Part E: Site Costing and Funding
- ✓ Part F: Attachments – Site Specific Documents
- Part G: Declaration**

Complete SSA

HREA:



A screenshot of the left-hand menu for the HREA application form. The menu items are listed vertically, each with a green checkmark icon. The items are: Method Specific, Interventional/Clinical Trials research, Participant Specific, Project Details, Recruitment, Consent, Risk, Benefit, Data and Privacy, Generate HREA document, and Upload. The 'Generate HREA document' item is highlighted with a yellow background. Below the menu is a black button with the text 'HREC'.

- ✓ Method Specific
- ✓ Interventional/Clinical Trials research
- ✓ Participant Specific
- ✓ Project Details
- ✓ Recruitment
- ✓ Consent
- ✓ Risk
- ✓ Benefit
- ✗ Data and Privacy
- Generate HREA document**
- ✓ Upload

HREC



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Responding to a request for information – Ethics + SSA

The status will then change to:

 Information provided

You have completed the request
information.

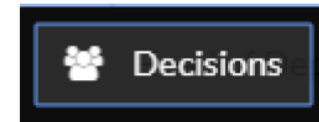


for

Checking HOD sign off

When you login to REGIS, you should be able to see the status of your project at any stage. Please select the relevant SSA and select 'Decisions'. You will be able to see which HOD you have selected and their responses / pending.

Click the 'Decisions' icon to view individual decisions and comments



A Decisions pop up will appear listing each individual decision:

- ❖ User: HOD
- ❖ Decision: Outcome
- ❖ Comment

User	Decision
Weninger, Wolfgang	able to undertake the investigations/services
Loblay, Robert	able to undertake the investigations/services
Twigg, Stephen	able to undertake the investigations/services

Head of Department - issues



Known bug – If HOD supports with conditions, then status will change to HOD not supported. Please call the office and we will be able to override this issue.

If the department you are looking for is not listed, please also contact the office to add the department to the list with person



There will be an enhancement to the system coming up in the next few months so that these known bugs will be fixed. It will also enable a HOD supported SSA to be submitted directly to the RGO without resubmission from the PI.



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Submission post HoD approval

Click the 'Options' (3 vertical dots) icon located next to the Identifier (STEXXXX) to open the application information menu



Click the **Application information** option to open the Application Details page

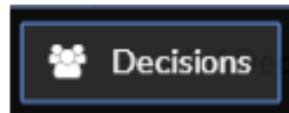
Select the 'Decisions' option on the left-hand menu



Click the 'Options' (3 vertical dots) icon located next to the Title



Click the 'Decisions' icon to view individual decisions and comments



Click the 'Options' (3 vertical dots) icon located next to the Head of Department Decision.

Click **Submit to RGO**



Please note: Only the site PI can submit to RGO.



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SSA Tips

- Ensure you select the correct Head of Departments such as Clinical Information, Pharmacy, Radiology, etc (if applicable).
- We don't need CV anymore, but we still need GCP for clinical trials, criminal record check for external investigators (to NSW Health) coming on site, and confidentiality agreement for external investigators (to NSW Health).



PATHOLOGY

Pathology has changed
– we no longer require
Pathology Head of
Department. However,
please upload the
Pathology quote in the
SSA documents.



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Ethics Checklist by Administration

The person listed as **CPI** when completing an ethics application must have the following response in HREA.

1.9.10 MUST be Coordinating Principal Investigator.

1.9.11 MUST have Yes selected.



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Ethics Checklist by Administration

In Part C of the project registration, list all sites where this research project will be conducted. Add these under the relevant jurisdictional tabs, i.e. ACT Health, NSW Health or Other. This step assists in generating SSA(s) if required, and provides a list of all nominated sites for HREC consideration.



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Ethics Checklist by Administration

Data should be stored securely for a minimum of 5 years, or 15 years for a clinical trial, or 25 years for clinical trials involving minors



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Ethics Checklist by Administration

Sites – *NSW Public Health Organisations are acceptable.*

If any of the proposed sites are private sites, please submit an External Entity Agreement (EEA) for each private site that will require ethical review. Please note there is a \$150.00 fee for each site that is not a Public Health Organisation. Please note we cannot provide ethics review for non-PHO sites outside NSW. If non-PHO sites outside NSW are involved in the study, a separate ethics application to the relevant authority will be required.

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.



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Ethics Checklist by Administration

Data linkage only applies if you are linking NSW Health data with data from other government agencies such as Medicare, Centrelink etc. Projects that only involve data within NSW Health usually do not satisfy data linkage.

If Data linkage or Clinical Trials Research is ticked then this will automatically prompt us that the study is Greater than Low Risk. Same goes if the research method or any vulnerable population in Q1.17 and Q1.19 is ticked.



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Ethics Checklist by Administration

- A substantial **Protocol** is received (i.e not half a page).
- Please ensure the protocol has a footer that lists the name of the document, version number and date.
- Highly recommended to use the template from our Research Directorate website. This document has the headings, footer and contents page all set up.



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Ethics Checklist by Administration

MASTER Documents

- Do not display the SWSLHD logo
- Do not have any site specific information such as the site name, investigator names, contact details, etc
- 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*

Please ensure all documents contain a footer that lists the name of the document, version number and date.



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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

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

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

Phone: 1300 073 447



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Questions



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