Ethics and Research Governance Workshop Series

Post Approval Requirements

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Research Ethics and Governance Administration Officer

NSW GOVERNMENT Health
South Western Sydney Local Health District

Please save questions for the end, as your question may be answered in this presentation ☺

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Overview

- Ethics Amendments
- Governance Amendments
- Annual Reports
- Site Annual Reports
- Addition of Associate Investigator

Review/Approval Process for Research in SWSLHD

Ethical Review (HREA)

- *Ethics Committee/Sub Committee (HREC)*

Governance Review (SSA)

- *Reviewed by Research Governance Officer (RGO)*

Approved / Authorised to Commence

- *Every study requires*
  - ***approval*** *from the HREC*
  - ***authorisation*** *from the RGO*

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Ethics Amendment

Used to update the Ethics component of the Research Project after approval.

Split into four types:

- Addition of Site
- Request for Extension
- Change of CPI/PI
- General Amendment

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Ethics Amendment - Addition of Site

Used to add a new site to the study.

Once this amendment is approved, governance approval will need to be obtained for the new site:

A) NSW or ACT site this will be obtained through an SSA generated in REGIS.

B) non-NSW site, the Principal Investigator of the new Site will need to speak to the relevant RGO for advice on their SSA process.

Ethics Amendment – Request for Extension

Used to increase the duration of a study.

Requires all Annual Reports Milestones in REGIS to have been submitted before this Amendment type can be reviewed.

Once this Amendment is approved, the end date will automatically be updated in REGIS.

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Ethics Amendment – Change PI/CPI

Used to update the Coordinating Principal Investigator (CPI) or a Principal Investigator (PI).

For Clinical Trials, a GCP certificate and CV detailing Clinical Trials Research Experience is required.

If the Incoming CPI or PI is a Non-NSW Health Employee, a Confidentiality Privacy Declaration Form and a Criminal Record Check valid within the past 36 months is also required.

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Ethics Amendment - General

Used to advise the Research Directorate of any change affecting the conduct, design or methodology of the study.

Includes any changes to:

- Information previously given in the HREA
- Protocol
- Information Sheets and Consent forms
- Other supporting documentation for the study

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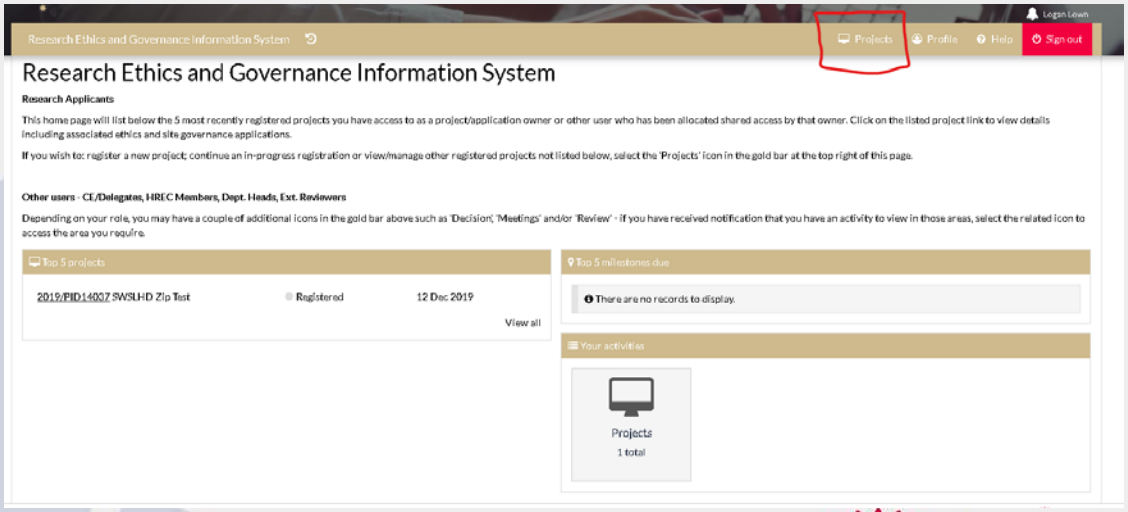
Ethics Amendment Process

Select the Projects button at the top right of the page → PID number for the study → ETH reference number.



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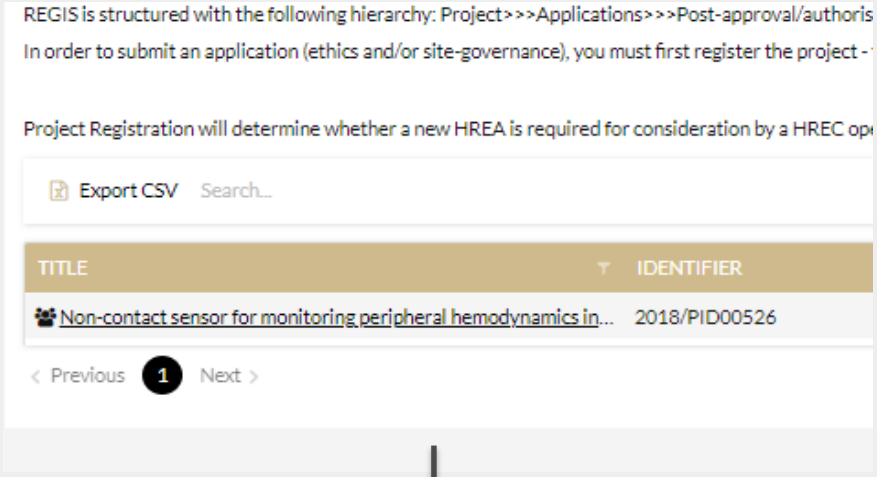

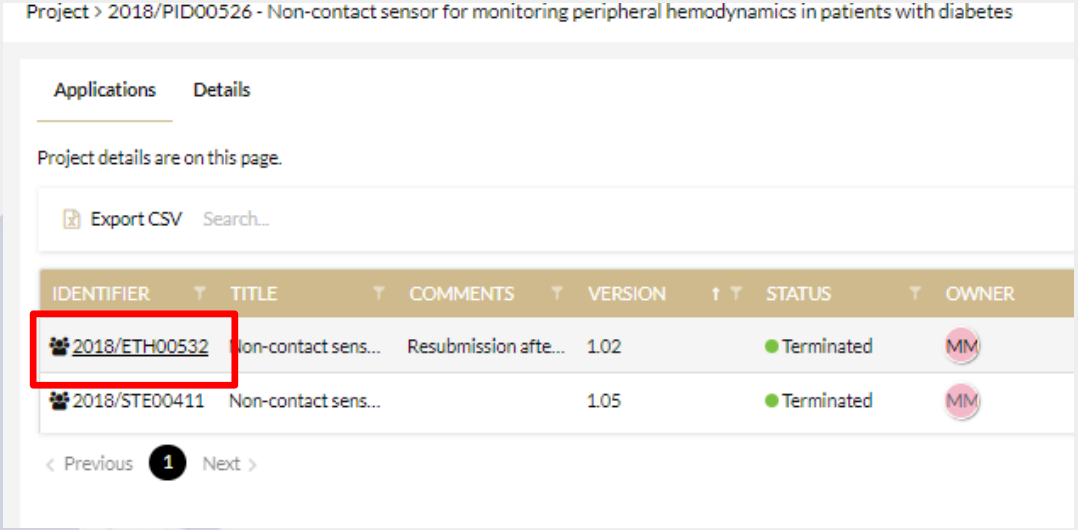

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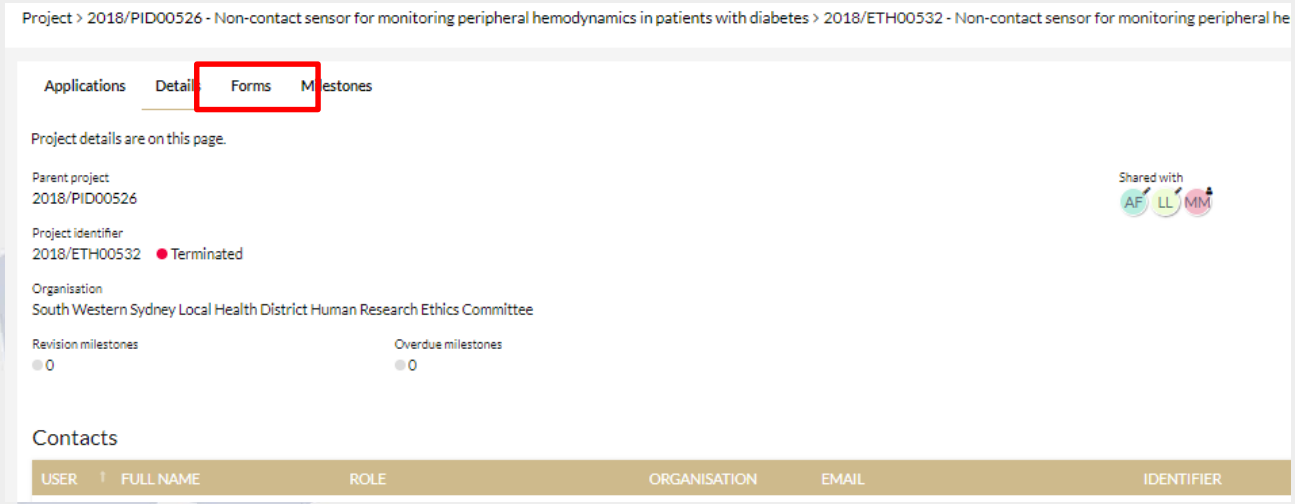
Ethics Amendment Process cont'd

Click on the Forms option at the top of the page → New Form in the top right hand side of the page → Notification of an Amendment to a Research Study in the pop-up box that appears.



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Project > 2018/PID00526 - Non-contact sensor for monitoring peripheral hemodynamics in patients with diabetes > 2018/ETH00532 - Non-contact sensor for monitoring peripheral hemodynamics in patients with diabetes

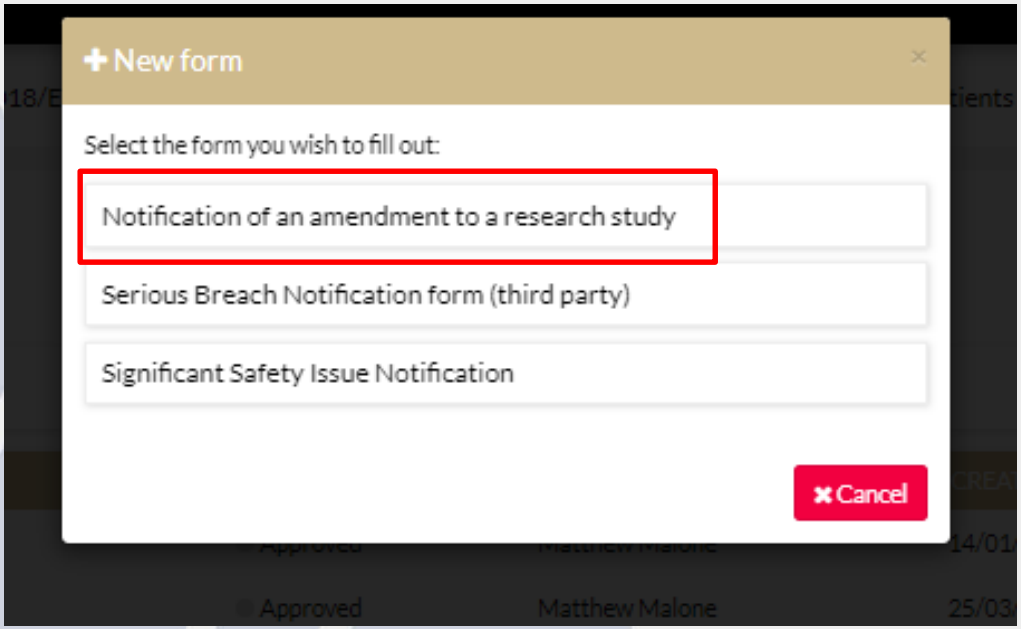
+New form

Applications Details Forms Milestones

Project forms details are on this page.

Export CSV

	TITLE	STATUS	OWNER	CREATED DATE	MODIFIED DATE	SUBMITTED DATE
⋮	004224 - Notification of an amendment to a research study	Approved	Matthew Malone	14/01/2019	12/02/2019	12/02/2019
⋮	006187 - Notification of an amendment to a research study	Approved	Matthew Malone	25/03/2019	25/03/2019	25/03/2019
⋮	017517 - Notification of an amendment to a research study	Approved	Matthew Malone	03/09/2019	12/09/2019	12/09/2019
⋮	018978 - Notification of an amendment to a research study	Approved	Matthew Malone	03/10/2019	03/10/2019	03/10/2019



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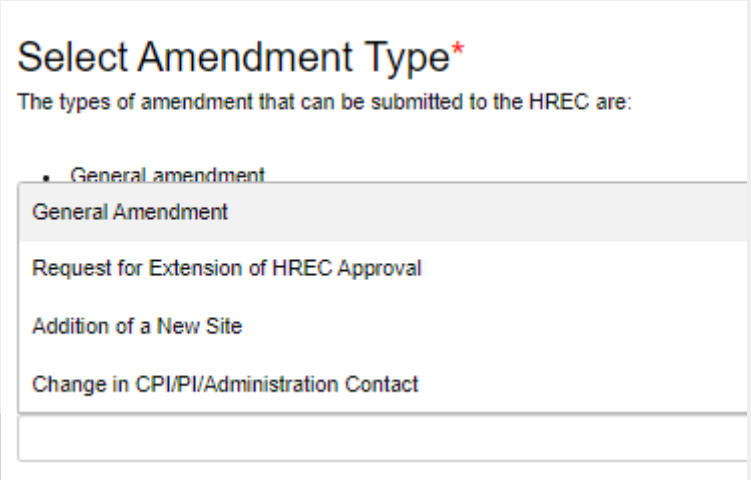
Ethics Amendment Process cont'd

Click on the Drop Down menu to select the Amendment type.



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Ethics Amendment Process – General Amendment

Summary of Modification, Rationale and Ethical Issue boxes

Add all updated and new documents in the Document Upload page

Complete the Coordinating Principal Investigator Declaration & submit

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Ethics Amendment Process – Addition of Site

Add the new Site details in the Addition of New Site tab

↓

Complete the Conflict of Interest declaration

↓

Add all updated and new documents in the Document Upload page

↓

Complete the Coordinating Principal Investigator Declaration & submit

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Ethics Amendment Process – Request for Extension of HREC Approval

Add reasons for the amendment and the requested updated Approval End Date

Add all updated and new documents in the Document Upload page

Complete the Coordinating Principal Investigator Declaration & submit

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Ethics Amendment Process – Change in CPI/PI

Select the option of either CPI, PI (NSW Health Sites/Sites exist in REGIS) or PI (All Other/Non REGIS)

↓

Complete the Reason for Change box, details of the new CPI or PI, Research Activities and Relevant Experience

↓

Complete the Conflict of Interest declaration

↓

Add all updated and new documents in the Document Upload page

↓

Complete the Coordinating Principal Investigator Declaration & submit

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No. 1 Rule for Ethics Amendment

All updated documents must be provided in both a Tracked and Clean copy, with an updated Version Number and Date in the document footer.

Any new documents can be provided in a Clean copy only, with a Version Number, Date and Document Name in the footer. See formatting example below:

[Document Title], Version XX, Dated XX/XX/XXXX

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Site Amendment

Used to submit documents to the Research Directorate that have been approved by a HREC that is not SWSLHD HREC.

Can be submitted via REGIS or by Email at swslhd-ethics@health.nsw.gov.au

Requires a completed SWSLHD Site Amendment Cover Letter

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Site Amendment – Email Submission

Complete the SWSLHD Site Amendment Cover Letter. Ensure that all documents are listed in the Cover Letter.

If there are Site Specific Documents (eg Participant Information Sheet), list these in the Site Specific table in the Site Amendment Cover Letter.

Provide the following:

- Site Amendment Cover Letter
- HREC Approval Letter
- All documents listed on the HREC Approval Letter
- Any Site Specific documents

Please number the documents in the same order that they are listed in the Site Amendment Cover Letter.

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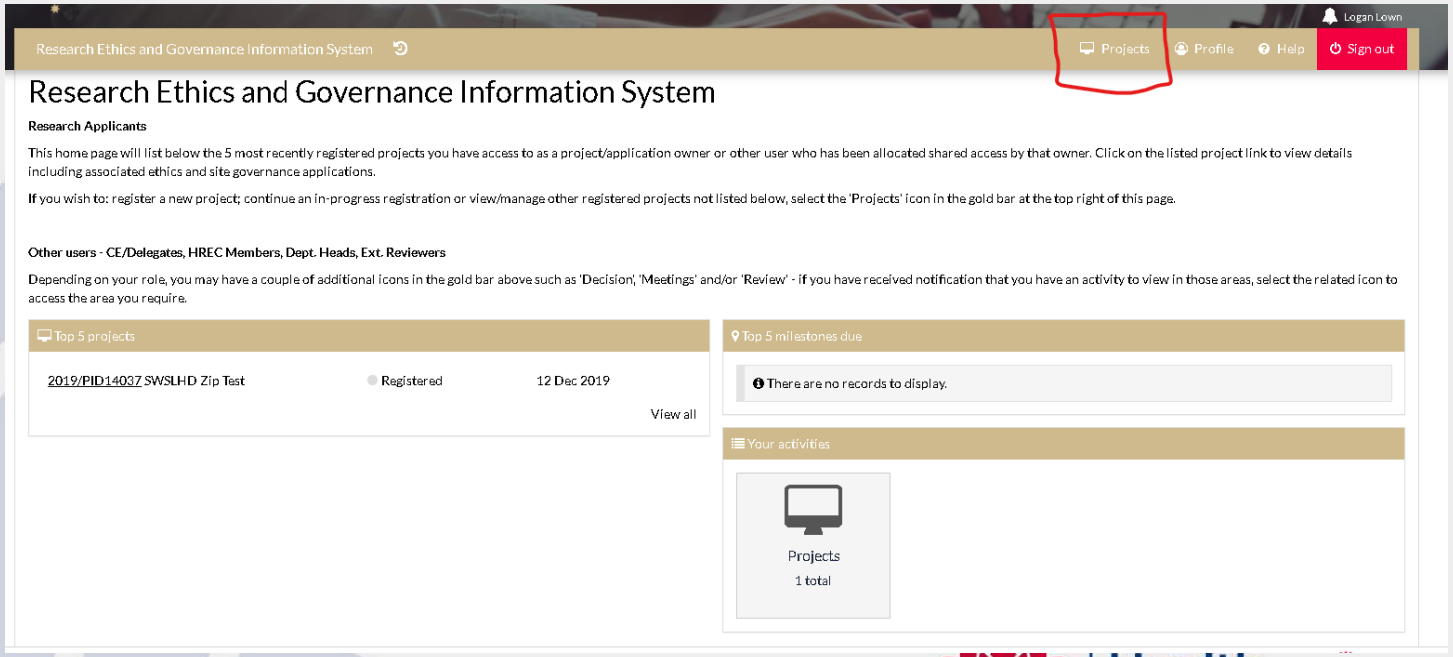
Site Amendment – REGIS Submission

Locate the Ethics Project by clicking on the Projects button at the top right of the page → PID number for the study → STE reference number.



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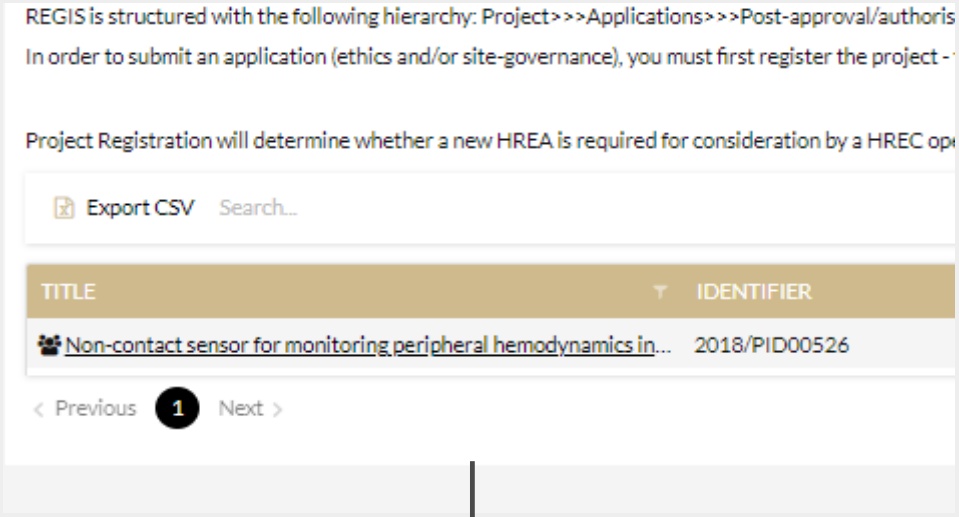

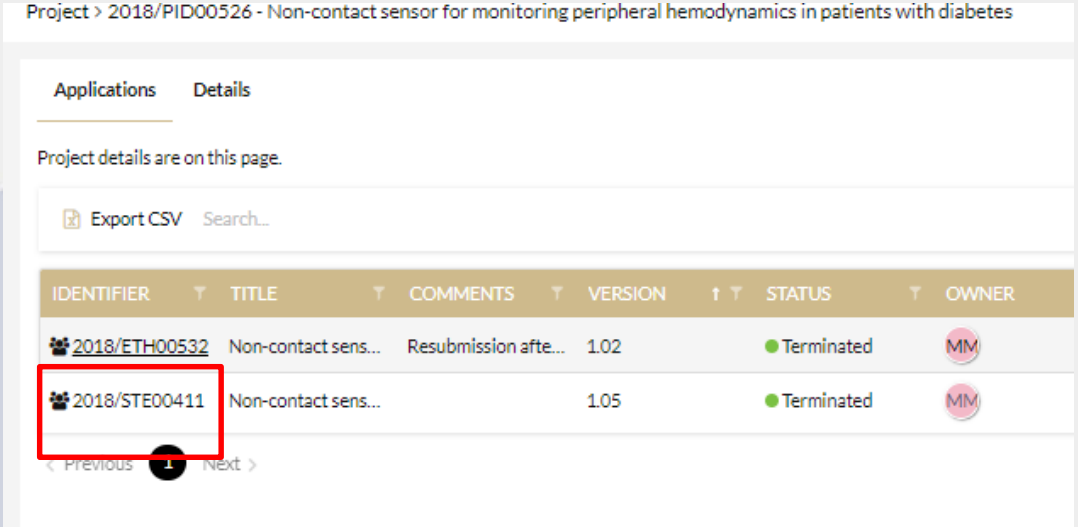

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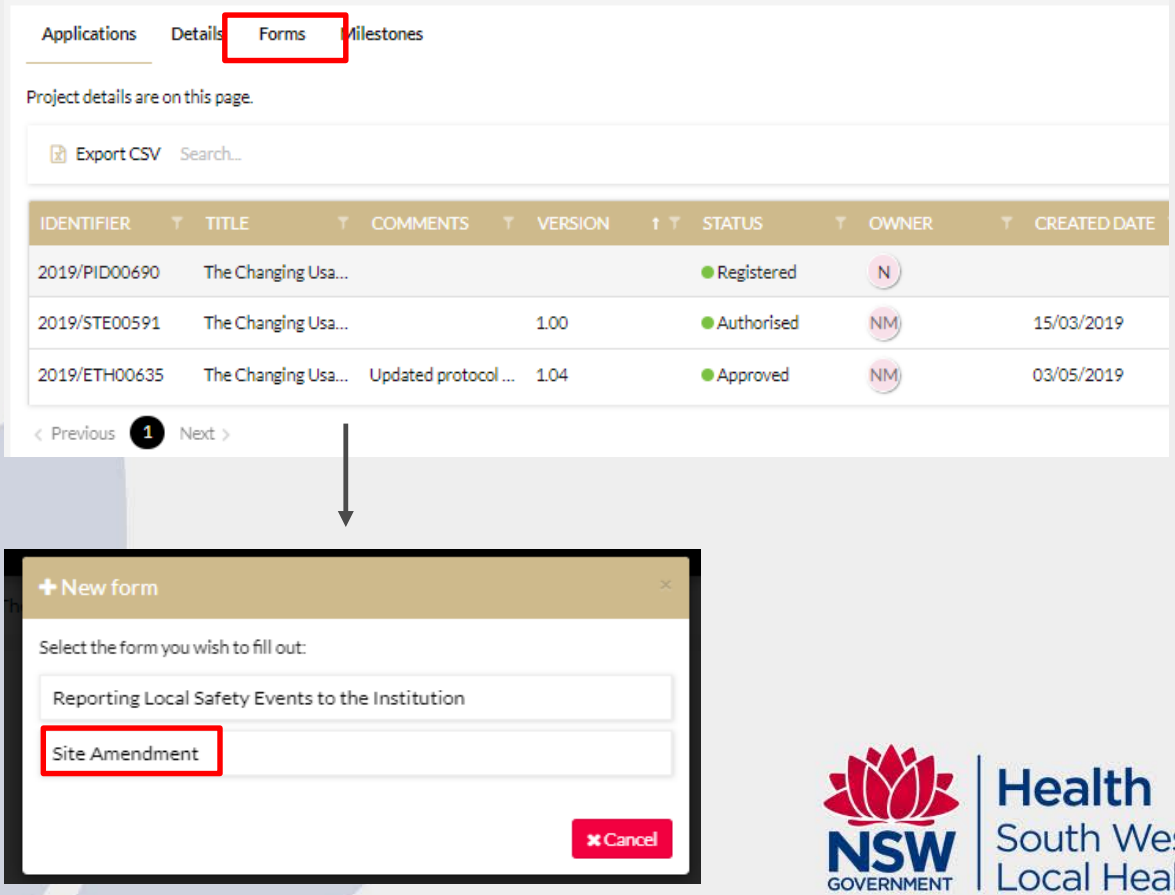
Site Amendment – REGIS Submission

Click on the Forms option at the top of the page → New Form appears in the centre of the page → Site Amendment in the pop-up box that appears.



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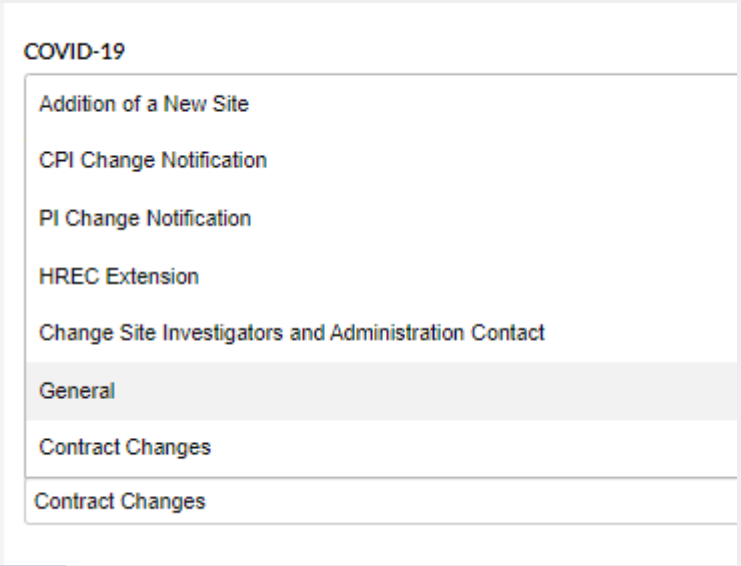
Site Amendment – REGIS Submission

For General Site Amendments, select General Amendment from the drop down menu. For Contract Changes, select Contract Changes in the drop down menu.



Do NOT select the other Site Amendment options for any study where lead HREC is within REGIS.

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Site Amendment – REGIS Submission General Amendment

Complete the required fields in the Site Amendment

↓

Add the Ethics Amendment Form ID if the Ethics Amendment was processed by a NSW or ACT HREC

↓

Add the completed Site Amendment Cover Letter, HREC Approval Letter, all documents listed on the Approval Letter and any Site Specific documents in a single Zip file

↓

Complete the PI Declaration & submit

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Site Amendment – REGIS Submission Contract Changes

Complete the Outline of Changes

Add the completed Site Amendment Cover Letter and updated Contract in Tracked and Clean in a single Zip file

Complete the PI Declaration & submit

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Site Amendment – General Information

Ensure that the Site Specific documents contain a Site Specific Footer with the Site Version Number, Date and Document name as well as containing the MASTER footer from the Approved MASTER documents. See formatting example below:

[MASTER Document Title], Version XX, Dated XX/XX/XXXX
(Site Name) [Document Title], Site Version XX, Dated XX/XX/XXXX

The Site Amendment Cover Letter will be signed and dated as the Site Amendment Approval from SWSLHD RGO.

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Annual Reports

An Annual Report Milestone needs to be submitted on every anniversary date of the Ethics Approval for a study.

The Final Report can be submitted prior to the anniversary date of the Ethics Approval.

Request for Extension of Ethics amendments cannot be submitted until all Annual Reports have been submitted.

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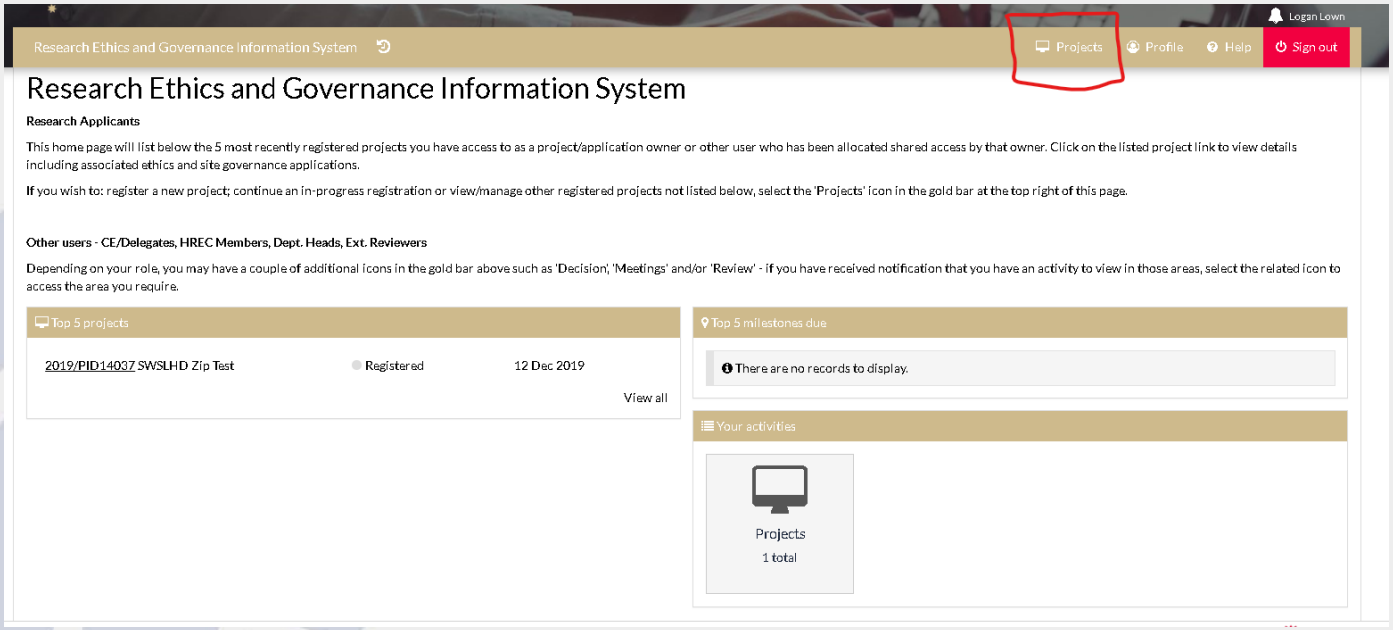
Annual Report Status Definitions

When completing an Annual Report, the following statuses can be selected:

- Not yet commenced
- In progress
- Completed
- Closed (post analysis)
- Abandoned
- Terminated

Annual Reports Process

Select Projects → PID Reference number → ETH reference number → Milestones.



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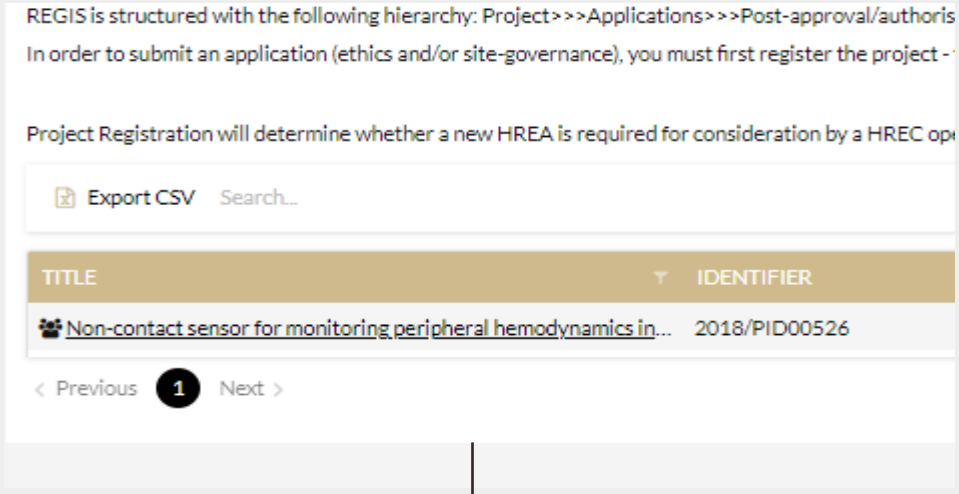

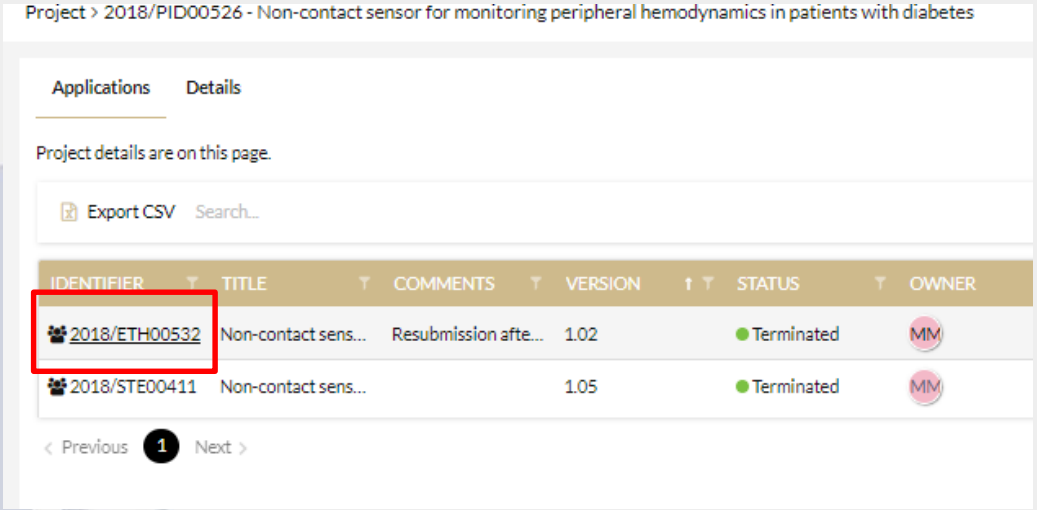

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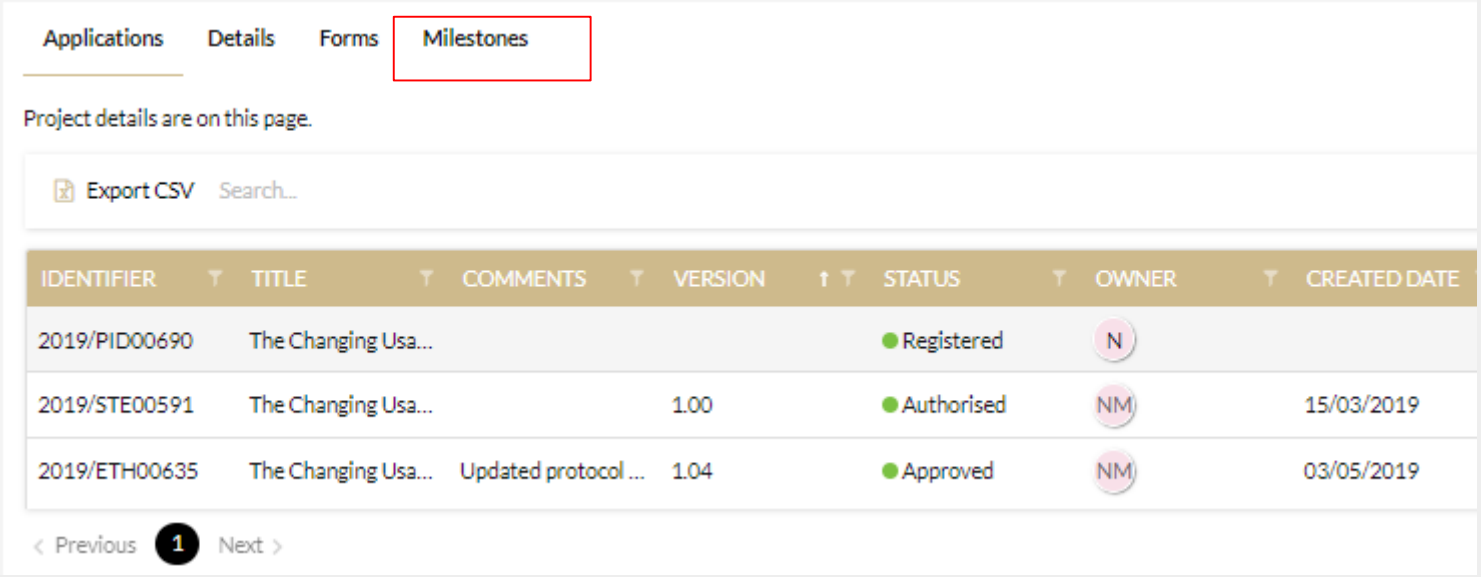

Complete the information in the form, upload any additional documents in the Document Upload section and then have the CPI submit the report.

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Site Annual Reports

A Site Annual Report needs to be submitted to our RGO once an Ethics Annual Report has been approved.

For studies with Ethics in REGIS, the Site Annual Report will be automatically submitted to our office when the Ethics Annual Report has been Approved.

For studies with Ethics external to REGIS, please submit the Ethics Annual Report to our RGO following the Site Amendment process outlined previously.

Addition of Investigator

Used to add associate investigators to a study site and submit via email.

If the investigator is not a NSW Health Employee, the following documentation is required:

- Declaration of Researchers
- GCP Certificate (for Clinical Trials only)
- Confidentiality Privacy Declaration Form
- Criminal Record Check completed within the past 36 months (if working on-site, contacting patients or viewing SWSLHD patient data)

If the investigator is a NSW Health Employee, the following documentation is required:

- Declaration of Researchers
- GCP Certificate (for Clinical Trials only)

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Safety Events

All safety events are to be emailed to swslhd-ethics@health.nsw.gov.au. Do not use REGIS for any safety event submissions.

Further information on safety events will be provided in a later presentation by Dr Cameron Lutman on 24 April 2023 at 2pm.

The presentation slides will be available on the Research Directorate website.

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REGIS User Guides

https://regis.health.nsw.gov.au/media/1723/qrg-resapp-ethics-amendment-completing-and-submitting.pdf

https://regis.health.nsw.gov.au/media/1722/qrg-resapp-ethics-amendment-responding-to-an-information-request.pdf

https://regis.health.nsw.gov.au/media/1724/qrg-resapp-submitting-progress-or-final-report-milestone.pdf

https://regis.health.nsw.gov.au/media/1729/qrg-resapp-governance-amendment-completing-and-submitting.pdf

https://regis.health.nsw.gov.au/media/1731/qrg-resapp-governance-amendment-responding-to-an-information-request.pdf

https://regis.health.nsw.gov.au/media/1730/qrg-resapp-submitting-governance-milestones.pdf

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Additional Documents

Documents such as the Confidentiality Declaration form and the SWSLHD Site Amendment Cover Letter can be found on the Research Directorate website at the below link:

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

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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).

E-mail: SWSLHD-Ethics@health.nsw.gov.au
Website: http://www.swslhd.nsw.gov.au/ethics/
Phone: 02 8738 8304 / 02 8738 8314

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

Thank you for listening

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