

# **SWSLHD REGIS Training Frequently Asked Questions**

**Malina Peng and Logan Lown – Administration Officers**

**Tegan Roberts – A/Research and Ethics Coordinator**

**Andrea Lee – A/Research Ethics and Governance Manager**

**Research Directorate**



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# Terms of Reference in REGIS

Application = Pre approval

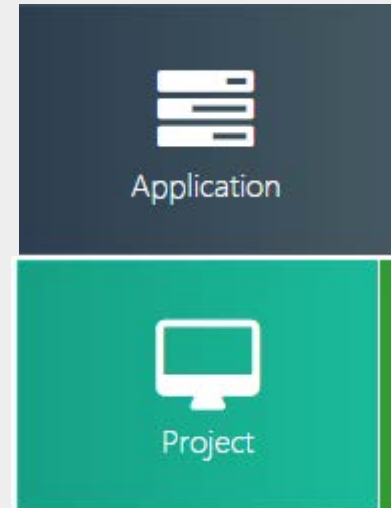
Project = Post approval

HREC Reference # = 2019/PIDXXXXX

Ethics Reference # = 2019/ETHXXXXX

Site Specific Reference # = 2019/STEXXXXX

Submit Project Registration to get access to Ethics and SSA.



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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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# Common issues, mistakes and omissions

- Contact the Research Office before submitting your application – we are happy to pre-review your draft protocol via email, and meet if necessary.
- Review your attachments to ensure there are no grammatical and spelling errors, etc.
- Ensure all documentation have title of document, version number and date.
- Don't forget to complete your SSA after your HREA.

The person listed as CPI during project registration must have the following response in HREA (this has been prefilled).

**1.9.10** **MUST** be Coordinating Principal Investigator.

**1.9.11** **MUST** have Yes selected



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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 required from the research team, the HREA status will be **Information Requested**. Please note that we require a response cover letter and updated documents in tracked and clean with the response in REGIS.
6. To submit further information, follow [QRG: Responding to a Request for Information – Initial Application and the instructions provided in the email from REGIS](#). 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.



# SSA – Status Flowchart

1. **Submitted** when you submit the SSA.
2. **Eligible /Ineligible** after administration checks are done.
3. If **ineligible**, follow *QRG – Resubmit a new version of the application after an ineligible notification*. The SSA will then go back to **submitted**.
4. If further clarification is required from the research team, the SSA status will either be **Information Requested or In Progress**. Please note that we require a response cover letter and updated documents in tracked and clean when responding in REGIS.
5. 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 pending review/action.
6. If the application is ready for approval as deemed by the Research Directorate, the SSA will be **Authorised**. You will receive an authorisation email via REGIS.



# 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



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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.

**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.

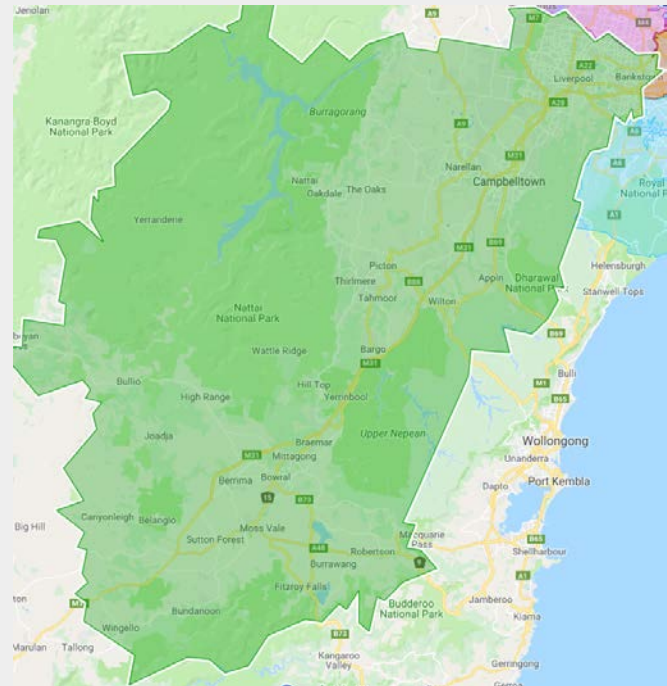


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# SWSLHD Sites

- Bankstown Lidcombe Hospital
- Bowral and District Hospital
- Camden Hospital
- Campbelltown Hospital
- Fairfield Hospital
- Ingham Institute for Applied Medical Research
- Karitane
- Liverpool Hospital
- NSW Office of Preventive Health
- NSW Service for the Treatment and Rehabilitation of Torture and Trauma Survivors (STARTTS)
- South Western Sydney Local Health District (Site)
- SWSLHD Community Health Centres



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# Ethics Amendment Types in REGIS

## Notification of an amendment to a research study

Project Details and  
Amendment Type

### Project Details and Amendment Type

Amendments are changes made to a research project or the terms of the HREC approval and/or Site Specific Authorisation after review body approval has been granted. REGIS is currently configured only for amendments to be reviewed by the office for guidance.

When amendments are made to a study, the HREC will consider how the change may impact on the rights, safety and wellbeing of participants, and the reliability and robustness of the study. Each study site also needs to be notified, and the study.

#### Project details (read-only):

Project Title

A Multicenter, Prospective Observational Study to Characterize the Clinical Course of Pregnant Women and Children at High Risk for Early Onset Severe Hemolytic Disease of the Fetus and Newborn

Ethics application no.

Lead HREC

Coordinating Principal Investigator

Sponsor

Sponsor Contact (Australia)

#### Amendment type\*

**General amendments** are those that impact on the conduct, the design, or the methodology of a trial and include:

- (a) Amendment to information previously given on the HREA.
- (b) Amendments to the protocol *note: if the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be provided.*
- (c) Amendment to the information sheet(s) and consent form/s for participants, or to any other supporting documentation for the study.

**Request for extension of HREC approval** should be completed if a researcher/sponsor wishes to extend the project beyond the original period granted by the HREC

**Addition of a New Site:** You must update the study details of the additional site(s) and investigator(s) so that an SSA for each new site can be generated and the new site investigators are notified

**Change in PI/CP:** You are only required to notify the HREC of changes to the Coordinating Principal Investigator and/or site Principal Investigator(s). The relevant research offices will similarly need to be notified.

Please select one from the drop-down list

General Amendment  
Request for Extension of HREC Approval  
Addition of a New Site  
Change in PI/CP

Different forms for different purposes  
and/or requiring change in system.



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# Amendment – Change PI/CPI

Only the existing PI/CPI can submit this form (to provide authority for the change of responsibility in absence of signatures on REGIS).

The form now delineates between NSW Health PIs and Other PIs. PIs that fall under the “PI (All Other)” category are not required to have a REGIS account.

If there are issues with contacting the PI/CPI to conduct this change in extenuating circumstances (i.e. unexpected leave, illness, etc.), please contact the Research Office so that we can assist.



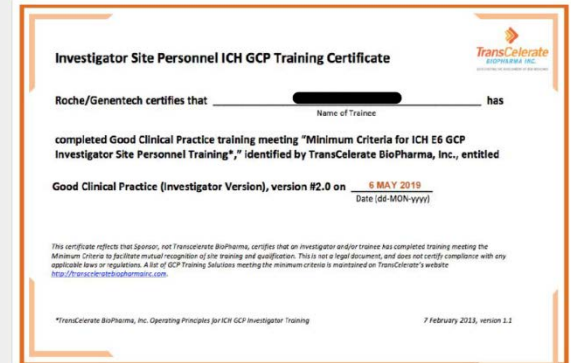
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# General Amendment: Addition of Investigators for ETHICS

Documentation required:

All clinical trials – GCP certification  
(valid for 3 years) from a transcelerate  
provider



**Make sure REGIS Profile is completed!**

Non-NSW health employees:

- Criminal Record Check – if working on site (valid for 12 months)
- Confidentiality Statement



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# Addition of Investigators for SSA where we are NOT LEAD HREC

- REGIS does not have functionality at this time for SSA/governance amendments.
- This means if SWSLHD is not the lead HREC for your project, you are unable to submit an amendment to add an investigator to a SWSLHD site in REGIS.
- Please submit Addition of Investigator using the old method (i.e. Addition of Investigator form from SWSLHD Research website and submit via email to [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au) )
- If you are unsure, contact us 😊



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# Amendment - Addition of site

✔ Project Details and Amendment Type

**Addition of New Research Site/s**

✔ Conflict of interests

✔ Document upload

✔ Coordinating Principal Investigator/Reporter's Declaration

## Addition of New Research Site/s

In the tabbed sections below, you will be required to nominate the sites at which you intend to undertake the activities for the project you are registering. Depending on the details of your project, you may need to enter sites under more than one tab.

You can **add** a site under the required tab/s by selecting the '+' icon. For locations with ACT Health or NSW Health, you will then select the relevant Centre/s and their associated site/s from pre-populated drop-down lists. For locations not operated by either government organisation, you will provide details as indicated.

If you wish to **delete** a site that you have listed below, select the tick box next to the Project Centre label and then select '-' in the gold bar below the section.

**Before proceeding, please note:**

All PIs named in this section must have a REGIS user profile before you will be able to complete registration - as you enter the PI email address, REGIS will search for a match with a registered user.

**If a match is found**, their email address will display for you to select and their full name will be added below. As you progress, REGIS will prepopulate registration and subsequent applications with relevant details from their profile as required.

**If no match is found**, leave the PI email blank and select 'Invite to Register'. This will open a dialogue box for you to add the PIs username (email address) and, when you save the dialogue box to close, your PI will receive an invite to register in REGIS at the email address you've entered. Once they can confirm they have registered their profile, come back and complete your registration. In the meantime, select the next section to complete from the menu down the left-side of the page

**Invite to register**

ACT Health   NSW Health   Other health jurisdictions or organisations

Select a Principal Investigator for each Site

+ -

When a site falls under “Other health jurisdiction or organisation” the PI is no longer required to have a REGIS account.

# Amendment – Request for extension

From 1 June 2020 researchers will not be able to submit an amendment on a project if it has an overdue milestone (progress report).

**ⓘ THIS STUDY HAS AN OVERDUE MILESTONE/ANNUAL REPORT.**  
Submitting an annual report is a requirement of your HREC approval. You will need  
For guidance please see: [Submitting Annual Progress or Final Report \(Milestone\)](#)



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# Completed pending HOD

Research Ethics and Governance Information System

View Application | Projects | Applications (2019/ST) | Application Details (2019/ST) | Application Approvals (2019/ST) | Sign out

Application

2019/PID

Application Details

Contacts

**Decisions**

Documents

Forms

History

Applications

Application details are on this page.

Application Decisions

Show 10 entries

Search:

	Approval	Created date	Outcome
Support for Site Specific Assessment	Liverpool Hospital	23/08/2019	able to undertake the investigations/services

Showing 1 to 1 of 1 entries

Submit to RGO

Submit to RGO

You can find out which HOD is pending by following the below steps:

- 1) Decision on the left menu
- 2) Click 3 dot menu next to HOD support for SSA
- 3) Select Decisions



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# Alternate A/HOD?

Click on the relevant STE  
Go to Part C:  
Departments  
Select from the drop down list under HOD name

Research Ethics and Governance Information System

C2. Department Head Name  
[Redacted]

C3. Department head email address \*  
[Redacted]@health.nsw.gov.au

C4. Please state the resources (e.g. staff, service/s, investigations etc) you require this department to provide: \*  
Investigations - to perform MRI  
Staff - to report on the MRI

C1. Department \*  
BANK - Clinical Information/Medical Records

C2. Department Head Name  
[Redacted]@health.nsw.gov.au  
[Redacted]@health.nsw.gov.au  
[Redacted]@health.nsw.gov.au  
[Redacted]@health.nsw.gov.au

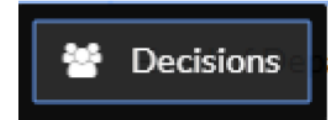
C4. Please state the resources (e.g. staff, service/s, investigations etc) you require this department to provide: \*  
To provide medical records /EMR



# Checking HOD support

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



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# + New Site button

Research Ethics and Governance Information System

Profile Projects Help Sign out

Home Projects Edit Application Applications (2019/2020)

Project

Project details

- Applications
- Contacts
- Details
- Documents
- History

Project details are on this page.

**!** New sites can only be added if the Ethics application has not been approved and is in the In Progress status.

**+ New Site**

Applications

Show 10 entries Search:

Identifier	Title	Version	Status	Owner	Created date
2019/ETH		1	Approved		29/01/2019 01:06:43 PM
2019		1	In Progress		30/01/2019 03:54:03 PM

Showing 1 to 2 of 2 entries

Previous 1 Next

Select the relevant PID number and +New site button should be visible



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# Administrative Contact

**Do you wish to provide details for an administrative contact for the project at this site to receive copies of notifications and other correspondence?\***

Please ensure this person already has a REGIS profile

Administrative contact required

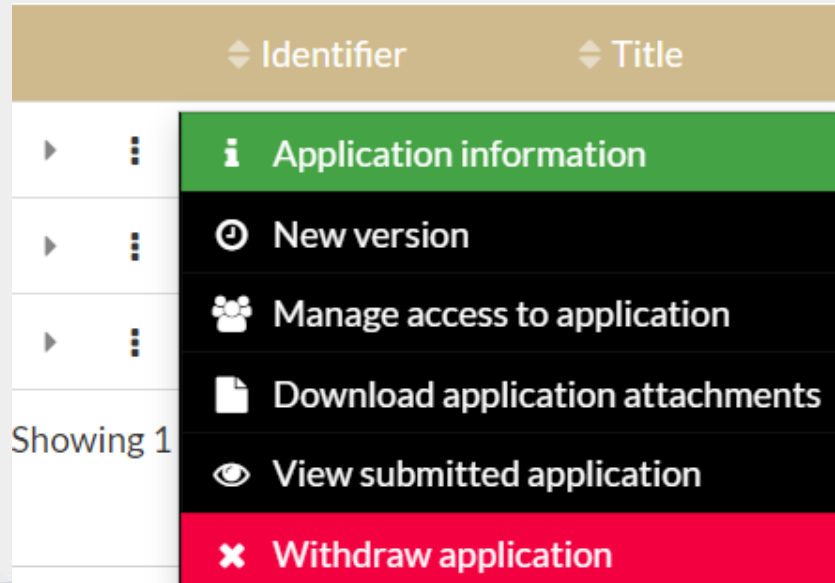
Admin. Contact email (REGIS username)\*

Ethics – list other contact to receive correspondences  
SSA – list contact person to receive correspondences



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# 3 dot menu options – Ethics/SSA



# Risk Pathway changed?

✓ Method Specific	Q4.5 Under which review pathway are you intending to submit this application? *
✓ Interventional/Clinical Trials research	• Before answering this question, consider the guidance provided by the institution to which you are applying and contact the ethics or research office for advice.
✓ Participant Specific	Greater than low risk review pathway
✓ Project Details	<b>Note: The institution to which you are applying will review your application and determine the level of risk of the research project. Your answer to this question will only inform them of the intended review pathway.</b>
✓ Recruitment	Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme? *
✓ Consent	<input type="radio"/> Yes <input checked="" type="radio"/> No
✓ Risk	
✓ Benefit	
✗ Data and Privacy	
✓ Generate HREA document	
✓ Upload	
HREC	

Click on the ETH number and scroll down to HREC tab on the left hand side menu. This is where the risk pathway can be updated.



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# Further Information Response – Ethics/SSA

Make requested changes to the HREA / SSA and upload a Zip file labelled Response (date) (including a completed version of this Response Cover Letter in the “Document Upload” section. NOTE: if the documents have not been uploaded in a Zip file, the response will be rejected. Only updated / new / requested documents should be included in the Zip file. If the Zip file is larger than 10MB, please separate the documents into multiple Zip files that are each less than 10MB and number the Zip files accordingly.

Generate HREA / SSA Document. This will submit the application to the SWSLHD Research Directorate.





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# Document Upload

## Document upload

 Preview

 Save

 Previous

 Next

This section allows the applicant to submit either amended versions of documents already approved by the HREC or to submit new documents.

Submitting a "New Version" means to submit a new version of an approved document that is already physically located in REGIS.

e.g. Studies that have been migrated from a legacy system will have HREC approved documents but they will not yet be available to update in REGIS.

User should select "No" the first time a document is being entered into REGIS.

If you are unsure if the document exists in REGIS select "yes" if the document does not appear in the Document Title/Descriptor drop down change the response to "no" and follow the prompts.

Please upload one tracked-changed copy and one clean copy of each amended document with this form. Tracked copies of the form must have a unique filename.

Only upload documents to be reviewed by the HREC. Site Specific documents that relate to this amendment, should be submitted directly to the RGO.

If there are no documents to be uploaded select the checkbox and the 'U' icon and progress to the next section.

If there are any issues with the above instructions, select 'No' so that the system does not hinder you from uploading your document/s.



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# Further Information Response – Ethics/SSA

**NOTE:** It is recommended to use Internet Explorer or Google Chrome when uploading a Zip file, as these are the two browsers compatible with REGIS. Please also note that operating systems other than Windows may not create Zip files that can be uploaded into REGIS.

If you are not able to use Windows when creating the Zip file, you may need to upload the documents individually into REGIS.

**NOTE:** Only the CPI will be able to generate the HREA Document

Any changes made to any of your documents including the ***Participant Information Sheets, Consent Forms, Questionnaires, Surveys or the Study Protocol*** must be submitted in both **tracked and clean** versions with an updated version number and date in the document footer.



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# New Applications related to COVID-19

All new applications are asked if “the application directly related to COVID-19 Research?” Where the response is “Yes” a further question will be asked to describe the type of research.

For new applications where Ethics is in REGIS this will be in Project Registration, part B.

For all site applications this in the STE/SSA form Part A.

Is this new application directly related to COVID-19 Research? \*

Yes

No

New Study Type (select for a definition to appear): \*

New COVID-19 treatment

This study proposes to test a new therapy (of any sort) for the treatment/prevention of COVID-19 disease.



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# Pausing or withdrawing an application due to COVID-19

- **Pause (COVID)** Where RO have been directed to not progress non COVID-19 related reviews. This review is paused and will be completed at a later date.
- **Withdrawn (COVID)** The study is being reviewed but the applicant is withdrawing the application as a direct result of COVID-19

The applicant should email the Research Office managing the application and ask that the application be Paused or Withdrawn due to COVID-19. Where the applicant indicates a suspension or termination due to COVID- 19 the Research Office will change the status of the study to match.



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# Amendments relating to COVID-19

## COVID-19

Does this amendment have any relation to COVID-19? \*

Yes  No

Is this amendment to add a SARS-CoV-2 (COVID-19) test? \*

*This existing study is to be amended to add a test of study participants for the SAR*

Yes  No

Is this amendment to add a new COVID-19 related element ('other' category)?\*

*This existing study is to be amended to add a sub-study or other component, such, that does not relate to directly testing participants for the SARS-CoV-2 virus.*

Yes  No

Is this amendment to respond to wider COVID-19 situation? \*

*This existing study is to be amended to change an aspect due to government regul, monitoring, home delivery of study product to self-isolating participants, etc.*

Yes  No

Is the study being suspended due to COVID-19? \*

*This amendment proposes temporarily halting an existing study specifically due to*

Yes  No

Is the study being terminated due to COVID-19? \*

*This amendment proposes terminate an existing study specifically due to the impr,*

Yes  No

**Every** Amendment, Significant Safety Issue (SSI) and Final Report will ask if the action is due to COVID. **\*Please note for all SSIs, these are required to be submitted via email to the office\***

The Notification of an amendment to a research study asks 'Does this amendment have any relation to COVID-19?' If this question is answered 'Yes' then more questions will be generated



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# Final Report due to COVID-19

If a Progress Report is being submitted with a status of Terminated/Abandoned the researchers will be asked “Is the study being Terminated/Abandoned due to COVID-19?”

If the study status is Terminated/Abandoned the final report will be created with these additional COVID-19 questions. If CPI Decision is selected a final question will be asked.

Where a final report is termination due to COVID-19 the Research Office will change the status of the study in REGIS.

## Study status

Study status

Terminated/Abandoned

Definition: (Abandoned) The application has been approved/authorised, but it h discontinuation of a research project by the investigator or sponsor, wherein act "Complete" or "Closed (post analysis)".

Is the study being Terminated/Abandoned due to COVID-19? \*

Yes  No

Who made the decision to terminate this trial?

CPI Decision

CPI Decision

Sponsor Decision

Directive by Regulatory Body or Host Organisation

Please select the main reason for the terminator:

- Participant Safety Considerations
- Staff Shortages
- Inability to meet recruitment
- Other - Financial, Site Shutdown, IMP delivery issues etc.



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# Annual Report document

Click on the 3 dot menu next to ETH number and select Project Information

Research Ethics and Governance Information System

Home | Projects | Applications (2019/ PID: [redacted]) | Project Details (2019/ ETH: [redacted]) | Milestones (2019/ ETH: [redacted])

Project

2019/ PID: [redacted]

Project details are on this page.

Milestones

Milestone status summary

100% Achieved

Show 10 entries

Project Identifier	Name	Detail	Status	Days remaining	Due date
2019/ETH: [redacted]	Progress Report	Progress Report	Achieved	N/A	22 Apr 2019

In order to add documents to support your annual report submission, please go back to documents tab.



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# Annual Report

## HREC Approved Sites

**Table 1: REGIS Authorised Sites.** This table will pre-fill all NSW site applications that have been authorised in REGIS.

**Table 2: Other REGIS Sites.** This table will pre-fill all submitted NSW sites applications that are in REGIS but are not yet approved

**Table 3: Sites External to REGIS.** You will need to manually create this table to list all other HREC approved sites.

If a NSW Site is not appearing table 1 or 2 you may need to submit a Notification of Amendment - addition of site.

If a Principal Investigator is incorrectly listed in table 1 you will need to submit a Notification of Amendment - Change PI/CPI.

### REGIS Authorised Sites

Project Identifier ?	Site ?	Status ?	Principal Investigator ?	Date Authorised ?
2020/STE01314	Westmead Hospital	Authorised	Corinne McDonough	21/04/2020 12:00:00 AM

### Other REGIS Sites

Application Identifier ?	Site ?	Status ?	Principal Investigator ?
2020/STE01328	Gosford Hospital	Submitted	Ms Corinne McDonough

### Sites External to REGIS

Sites external to REGIS include any other sites not listed in the above 2 tables. This includes sites from other states/jurisdictions approved under NMA (VIC, SA, QLD, WA), private sites, University sites or NSW sites not included in REGIS. You can add more rows by clicking on the "+" icon at the bottom of this table.

Site Identifier ?	Site ?	Status ?	Principal Investigator ?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>



# 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](mailto: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](mailto:support@f1solutions.com.au)

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

Phone: 1300 073 447



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# Questions



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