# SWSLHD
# REGIS Training
# Submit what and where?

**Logan Lown**

**Research Directorate**

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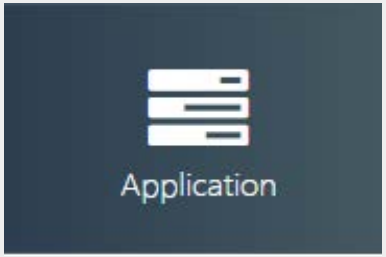
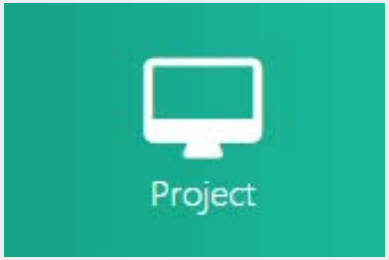
Local Health District

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

# 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 Ethics and SSA.

# REGIS Account

- To be an editor for an application, or to be listed as a Coordinating Principal Investigator or a Principal Investigator, you must have a REGIS Account.
- Your REGIS Account will link to your email address and any correspondence sent through REGIS will go to your nominated email address.
- Any data you put in your profile on REGIS will be pulled into applications you are involved in.
- REGIS can be linked to your ORCiD account.

- You can register an account from the Home Page of REGIS.
- If you believe that you have multiple accounts, you can merge them by contacting the help desk on 1300 073 447.
- After creating an account for the first time, click on the Profile button to customize your details. This will also allow you to check that you want Email Notifications.

# 3 Application Types

- There are three application types in REGIS that must be submitted for any project.
- Project Registration
- Ethics Application
- Governance Application (Site Specific Application)

# Creating a Project in REGIS

Logan Lown

Research Ethics and Governance Information System

Projects | Profile | Help | Sign out

## Research Ethics and Governance Information System

**Research Applicants**

This home page will list below the 5 most recently registered projects you have access to as a project/application owner or other user who has been allocated shared access by that owner. Click on the listed project link to view details including associated ethics and site governance applications.

If you wish to: register a new project; continue an in-progress registration or view/manage other registered projects not listed below, select the 'Projects' icon in the gold bar at the top right of this page.

**Other users - CE/Delegates, HREC Members, Dept. Heads, Ext. Reviewers**

Depending on your role, you may have a couple of additional icons in the gold bar above such as 'Decision', 'Meetings' and/or 'Review' - if you have received notification that you have an activity to view in those areas, select the related icon to access the area you require.

**Top 5 projects**

| | | |
|---|---|---|
| 2019/PID14037 SWSLHD Zip Test | Registered | 12 Dec 2019 |

View all

**Top 5 milestones due**

There are no records to display.

**Your activities**

Projects

1 total

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Research Ethics and Governance Information System

# Projects

REGIS is structured with the following hierarchy: Project>>>Applications>>>Post-approval/authorisation Amendments, Repor

In order to submit an application (ethics and/or site-governance), you must first register the project - you can do that here by sel

Project Registration will determine whether a new HREA is required for consideration by a HREC operating within ACT or NSV
details entered at registration pre-populate those subsequent applications.

Below are your projects. Click the link to open and manage your project.

+ New Project

Export CSV Show 10 entries

| Title | Identifier | Status | Ethics approved | Expiry date |
|---|---|---|---|---|

+ New Project

Select the form you wish to fill out:

Project Registration

Cancel

lications>>

low are all the p

you must fi

w.

red for consideration by a HREC operating within ACT or NSW health services and if SSA will need to be generated
lications.

your project.

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# New Project Registration

- Introduction
- Part A: Previous Ethics Application
- Part B: Project Details
- Part C: Research Site/s
- Part D: Coordinating Principal Investigator
- Part F: Upload Attachments
- Submit

## Part C: Research Site/s

Preview | Save | Previous | Next

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

**You must add at least one site in the below table.**

If you are unsure of the Project Centre use this cell to search NSW/ACT site names in REGIS.
Once you select the Project Site the Project Centre will appear. Use this information to complete the table below.

Liverpool Hospital | South Western Sydney Local Health District

ACT Health | NSW Health | Other health jurisdictions or organisations

**Nominate the project site/s within NSW Health and a Principal Investigator for each site**
A research project may be conducted at one or more sites within one or more Centres within NSW Health.

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If you are unsure of the Project Centre use this cell to search NSW/ACT site names in REGIS.
Once you select the Project Site the Project Centre will appear. Use this information to complete the table below.

Liverpool Hospital

South Western Sydney Local Health District

ACT Health | NSW Health | Other health jurisdictions or organisations

**Nominate the project site/s within NSW Health and a Principal Investigator for each site**
A research project may be conducted at one or more sites within one or more Centres within NSW Health.
A 'Centre' may be a Local Health District (LHD), a Specialty Health Network, a Pillar organisation, an affiliated health organisation or other health organisation operated by NSW Health. A Site Specific Assessment (SSA) will be generated for each site nominated.

A Principal Investigator (PI) is the person responsible either individually or as a leader of the researchers at a site, for the conduct of research at that site. In a single site research project or when a project does not require the appointment of a NSW Health principal investigator, the coordinating principal investigator may also be the principal investigator. The PI is the only person who has the authority to submit the Site application. An incorrect response here may cause the application to be Ineligible and will cause delay in processing.

If you are unsure of the names of the Centre or Site/s your project will be conducted at, **please discuss with your local research office. An incorrect selection here can delay your application process.**

Project Centre *: South Western Sydney Local Health District

Project Site *: Liverpool Hospital

Principal Investigator email (REGIS username) *: Logan.Lown@health.nsw.gov.au

Principle Investigator name: Logan Lown

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# Project Registration Important Notes

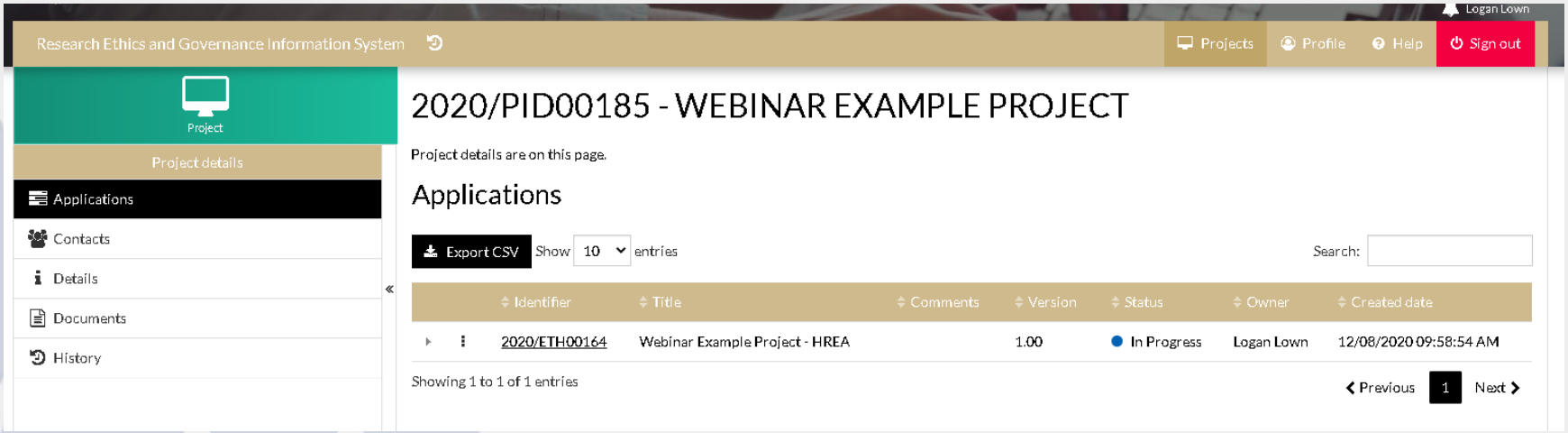
The Project Registration cannot be edited after it has been completed.

All Public Health Sites within NSW need to be listed in the Project Registration to generate an SSA within REGIS

If you have forgotten to add a site, and the Ethics application has not been approved, you can add new sites through the New Site option.

# Submitting an Ethics Application

After submitting your Project Registration, ad Ethics Application will appear in REGIS, as well as any Site Specific Applications based on the sites listed in the Project Registration.

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Q1.9.10 What is the position of this person on the research project? *

- The Chief Investigator, Co-ordinating Principal Investigator or Lead Investigator is the person with overall responsibility for the research project.
- For projects conducted at multiple sites, the Principal Investigator is the person with responsibility for managing the research project at each site.
- If you are a Co-ordinating Principal Investigator for the overall project and a Principal Investigator at a given site, list your role as Co-ordinating Principal Investigator.
- A person who does not have the above responsibilities is often referred to as an Associate /Assistant/Sub-/Co- Investigator or Investigator.
- Consult with your institution's ethics or research office for further advice on the terms used at your institution.

Co-ordinating Principal Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team? *

- NSW and Health Health PHO HRECs accept HREA submission by CPI on behalf of project team.

✔Yes No

Only the CPI can have the answer 'Yes' for question 1.9.11

All other investigators must have the answer 'No'

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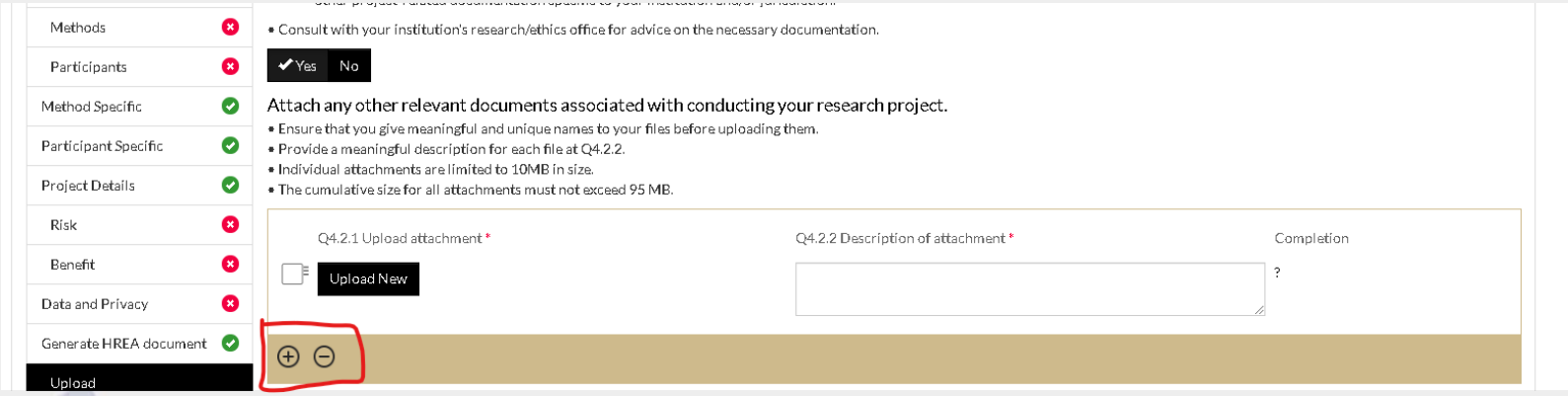
# Adding Documents




Use the + and – buttons in the gold bar to add or remove documents from the submission.

Please ensure that all documents have a footer containing the document version number and date.

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2020/ETH00164 - Webinar Example Project - HREA

- Introduction
- Project Overview
- Project Team
  - Project Team Details
    - *(1) Logan Lown*
    - *(2) Logan Lown*
  - Disclosure of Interests
  - Restrictions
  - Evaluations
  - Location
  - Methods
  - Participants

## Declaration

Preview | Save | Previous | Next

This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research team.

- Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team.
- You can use the share feature to have other researchers/investigators complete their declaration within this application – see the HREA How to Guide for details.
- You can upload evidence of the other researchers/investigators' agreement to this declaration (e.g. a PDF of an email).
- You can have researchers/investigators sign this application after it is completed and printed (i.e. a 'wet ink' signature).

- Ensure you answer Q1.9.11 for each team member before completing this section.
- Electronic acceptance linked to user profile.

Q4.7 **I, Logan Lown**, certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Certify

Only the CPI can click Certify and then Generate the HREA

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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. The response cover letter can be found on our website:

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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# What you need to submit with SSAs

- Ensure Master Documents are visible if HREC is not SWSLHD.
- If not SWSLHD HREC, provide all ethics approval letters.
- If Ethics is approved, submit your Site Specific Documents
- Only submit the latest version of each document – do not keep earlier versions that are now outdated in REGIS.
- Confidentiality Agreement for investigators not employed by NSW Health. Criminal Record check if they are also coming on-site, contacting participants or viewing identifiable information.
- If you have not filled in your REGIS Profile sufficiently, we will ask for a CV.
- For clinical trials: GCP training for all investigators current within last 3 years, CTRA, Indemnity (if applicable), insurance documents, SEBS approval letter for any changes to Schedule 7 of the CTRA, NSW Pathology quote (if applicable), Radiation Letter as submitted to HREC and the local SWSLHD Radiation Letter (if applicable).

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# Submitting an SSA Application

Documents

History

Export CSV Show 10 entries Search:

| Identifier | Title | Comments | Version | Status | Owner | Created date |
|---|---|---|---|---|---|---|
| 2019/ETH12546 | SWSLHD Zip Test | | 0.00 | Submitted | Logan Lown | 12/12/2019 03:48:00 PM |
| 2019/STE15827 | SWSLHD Zip Test | | 1.01 | In Progress | Logan Lown | 06/03/2020 09:36:18 AM |
| 2019/STE15828 | SWSLHD Zip Test - Campbelltown Hospital | | 1.00 | In Progress | Malina Peng | 12/12/2019 03:51:10 PM |

Showing 1 to 3 of 3 entries

Previous 1 Next

All NSW Public Health Sites listed in the Registration or added as an Addition of Site Amendment will be listed here

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# Adding Head of Department

Part B: Site Team

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

Identified against each nominated department.

*Please note: the 'Head of Department' for any NSW Health staff undertaking roles of either PI or back-up PI (an Associate Investigator) for this project at this site must be listed in this section.*

A pre-populated declaration of support for each nominated department head (including a complete copy of this SSA and its attachments) will be generated on completion of this SSA utilising the information in this section. Each Head will be notified by email of the need for them to respond to the support request you submit.
Therefore, it is also important that you have approached the department head before completing this application to discuss the project and what it is you are requesting them to support. Depending on the project, this may include but is not limited to: allocation of staff time; use of facilities and/or equipment and/or access to data/records. While some projects may be funded to support their activities, others may require in-kind support.

***If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.***

C1. Department *

No department head can be found for the selected department.

C2. Department Head Name

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

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

A pre-populated declaration of support for each nominated department head (including a complete copy of this SSA and its attachments) will be generated on completion of this SSA utilising the information in this section. Each Head will be notified by email of the need for them to respond to the support request you submit.
Therefore, it is also important that you have approached the department head before completing this application to discuss the project and what it is you are requesting them to support. Depending on the project, this may include but is not limited to: allocation of staff time; use of facilities and/or equipment and/or access to data/records. While some projects may be funded to support their activities, others may require in-kind support.

***If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.***

C1. Department *

LIV - Clinical Information/Medical Records

C2. Department Head Name

Ashna Sharma

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You cannot select a Head of Department who is also listed an investigator in the study. If this occurs and you cannot manually change the Head of Department in REGIS, please contact our office.

If the correct Head of Department is not showing in REGIS and you cannot change this, please contact our office.

Only the PI can submit the SSA to the Research Office for review.

# 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 needed, SSA will either be **Information Requested**. Please note that we require a response cover letter and updated documents in tracked and clean.

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.

6. If the application is ready for approval as deemed by the Research Ethics Office, the SSA will be **Authorised**. You will receive an authorisation email via REGIS.

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# REGIS Tips!

- Please read the Quick Reference Guide if you are not familiar with using REGIS
- Please do not copy the application! Only create a **New Version** for replying to further information requests for both Ethics and SSA.
- Please do not forget your **Cover Letter** when reply to further information requests for both Ethics and SSA.

# Ethics Amendment Types in REGIS

Select the approval type:

- Amend Form (General Amend)
- Amend Form change PI/CPI
- Amend Form extension ethics
- Amend Form new site

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

# Notification of Amendment

## 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 reviewe 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 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

[redacted]

Ethics application no.

Coordinating Principal Investigator

[redacted]

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/CPI:** 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/CPI

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# Amendment – Change PI/CPI

- Self-explanatory – use only for changing PI/CPI of a study.
- NOTE: Only the existing PI/CPI can submit this form (to provide authority for the change of responsibility in absence of signatures on REGIS).
- 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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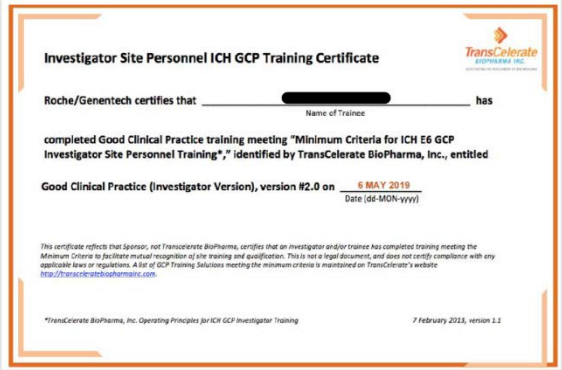
# General Amendment:
# Addition of Investigators for ETHICS

Documentation required:

All clinical trials – GCP certification (valid for 3 years)



Investigator Site Personnel ICH GCP Training Certificate

TransCelerate BIOPHARMA INC.

Roche/Genentech certifies that _____ has
Name of Trainee

completed Good Clinical Practice training meeting "Minimum Criteria for ICH E6 GCP Investigator Site Personnel Training*," identified by TransCelerate BioPharma, Inc., entitled

Good Clinical Practice (Investigator Version), version #2.0 on 6 MAY 2019
Date (dd-MON-yyyy)

*This certificate reflects that Sponsor, not Transcelerate BioPharma, certifies that an investigator and/or trainee has completed training meeting the Minimum Criteria to facilitate mutual recognition of site training and qualification. This is not a legal document, and does not certify compliance with any applicable laws or regulations. A list of GCP Training Solutions meeting the minimum criteria is maintained on TransCelerate's website http://transceleratebiopharmainc.com.*

**TransCelerate BioPharma, Inc. Operating Principles for ICH GCP Investigator Training* *7 February 2013, version 1.1*

**<u>Make sure REGIS Profile is completed!</u>**

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 Amendments.
- This means if SWSLHD is not 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 )
- If you are unsure, contact us ☺

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# General Amendment Information

- When submitting documents for a general amendment, please provide all updated documents in both Tracked and Clean versions.

- If the amendment requires further information, ensure that the SWSLHD Response Cover Letter has been completed, which can be found on our website.

# 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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