Ready Set REGIS!

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Subject Matter Expert
28 June 2019

REGIS
Research Ethics Governance Information System

@MedResearchNSW

NSW GOVERNMENT eHealth

Background

2012 The NSW Government undertook a strategic review of health and medical research in NSW.

Among the recommendations was the need to improve the information system to streamline ethics approval and site assessment processes.

2016 The contract end approached for the current system used in NSW (AU-RED/Online Forms)

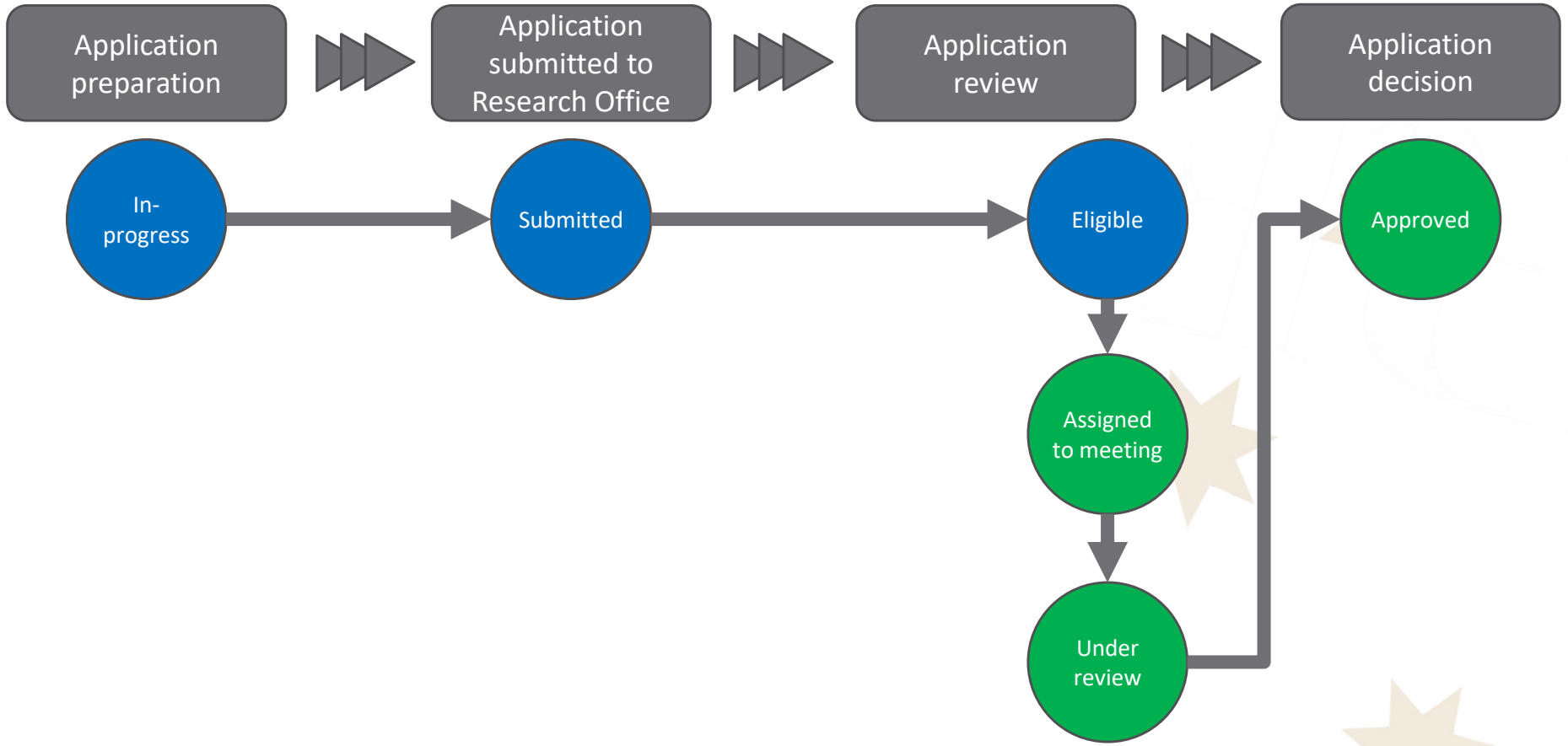
NSW Health was obliged to undertake a competitive procurement process.

2017 Solution developer, F1 Solutions Pty Limited, was announced at the successful tender.

2018 REGIS was soft launched into most NSW Health LHD's and ACT Health

Who are the users?

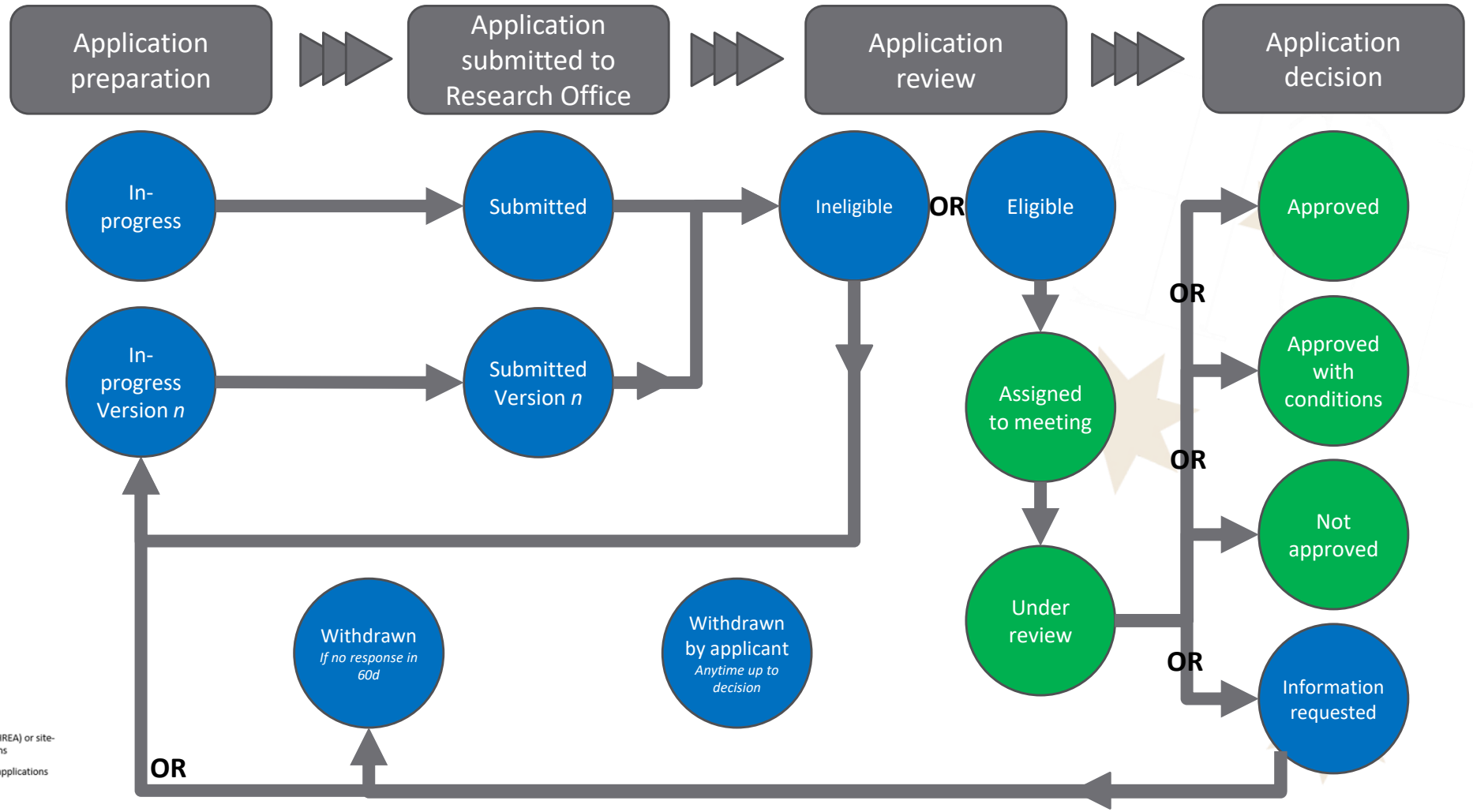
Application process - ETH (perfect application!)



Blue — may apply to either ethics (HREA) or site-governance (SSA) applications

Green — may apply to ethics (HREA) applications only

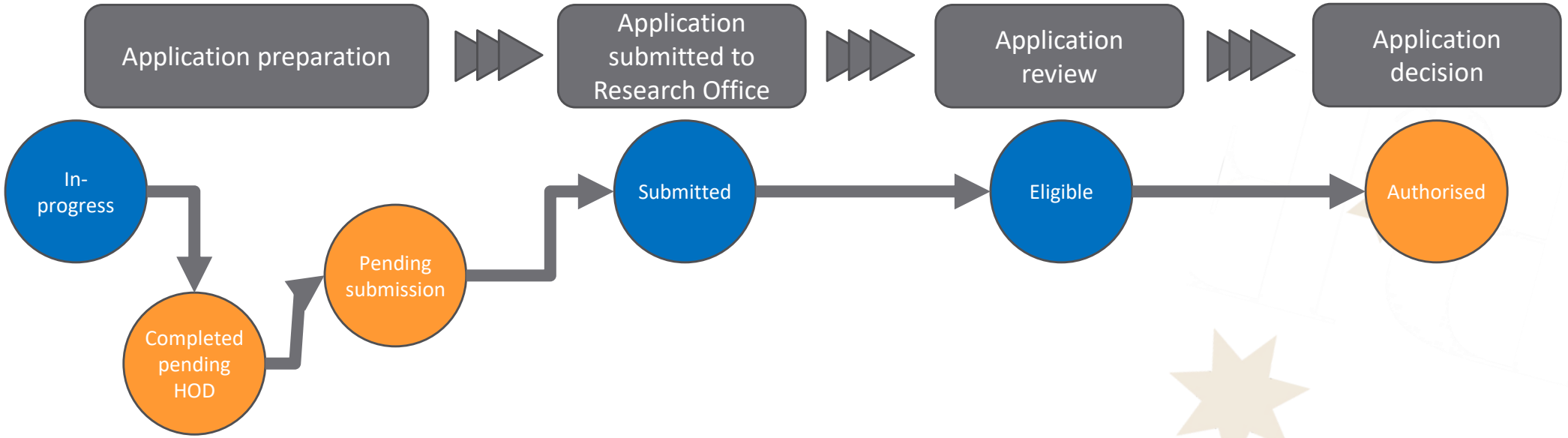
Application process - ETH



Blue may apply to either ethics (HREA) or site-governance (SSA) applications

Orange may apply to site-governance (SSA) applications

Application process - STE (perfect application!)



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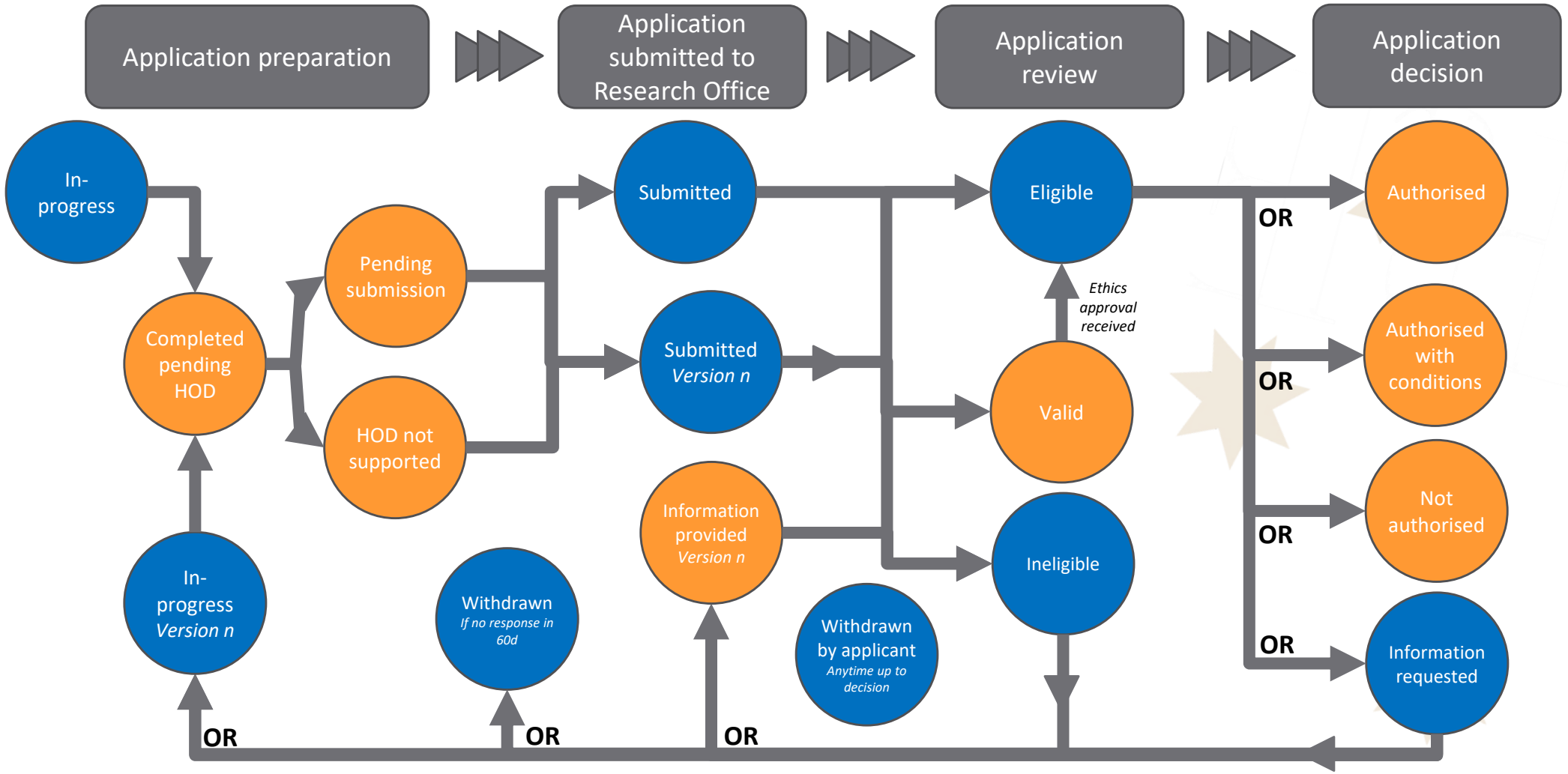
Orange — may apply to site-governance (SSA) applications

Application process - STE



REGIS Terminology (same, same but different)

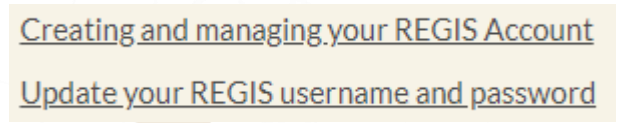
- Project Registration
  - Similar to a Minimum Dataset Form (MDF)
- Roles
  - **Coordinating Principal Investigator** – ETH the only person who has the authority to submit applications and forms for research at NSW Public Health Organisation HREC.
  - **Principal Investigator** - STE the only person who has the authority to submit applications and forms for research at NSW Public Health Organisation RGO.
  - The CPI and the PI may or may not be the same person depending on the size or the study.
- Share (don't transfer)
  - Anyone with a REGIS account (Sponsors, admin team) can have an application shared with them. Not required to be a team member on the application.
  - **Editor** - has access to view and edit the application/project. Can complete all actions except for submitting.
  - **Viewer** – has access to view the application/project but can not change.

Glossary

Sharing access to an application/project

Before you apply in REGIS

- Do the following people have a REGIS account?
  - Coordinating Principal Investigator (REGIS defined terminology/role)
  - Principal Investigator/s (REGIS defined terminology/role)
  - Associate Investigators (for clinical trials only)
  - Admin Contacts
  - Anyone who needs Edit or View of the access of the application
- Contact the Research Office managing the application/s
  - Do they have a checklist?
  - Confirm the NSW sites to be entered at Project Registration
- Electronic documents to be uploaded with the application
  - Filenames should NOT contain version numbers or dates (these would still appear in the document)
  - This will assist REGIS in successfully managing versioning in the system
  - Shorten the amount of time it takes a research office to create an approval notification

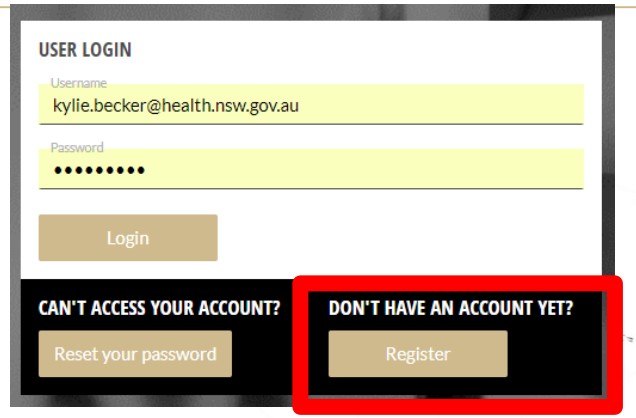


Before you apply in REGIS (cont)

- Create a REGIS login

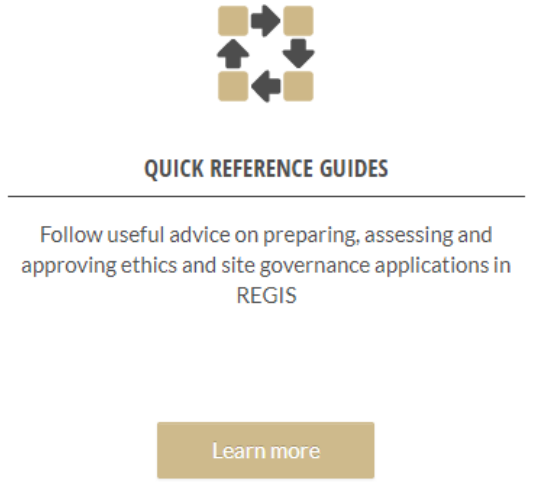
https://regis.health.nsw.gov.au/

Username = email = email that should appear in the applications



- Read Quick Reference Guides

https://regis.health.nsw.gov.au/how-to/



Project Registration

- All NEW applications in NSW start with Project Registration (similar to a minimum dataset form)

- **ANYONE** with a REGIS account **can complete AND submit** Project Registration

- Captures project level information that is shared between the Ethics and Governance Applications (reducing duplication). Provides the system specific information that reduces effort through the life of the application/project.

Project Registration – Hints for success

- Read on page instructions

Introduction

Registration of your human research project is the first step to initiation of ethics and/or site governance applications in REGIS. Please ensure you are familiar with the requirements for human research of the relevant health jurisdiction within which your project will be undertaken before proceeding.

ACT Health Research Ethics and Governance Office
NSW Health Office of Health and Medical Research (OHMR)

Information entered during registration will help identify if either an ethics application (HREA – Human Research Ethics Application) and/or site governance application/s (SSA - Site Specific Assessment) will need to be generated by REGIS for your project.

Project Registration also assists in determining what else might need to be provided to complete your application/s in response to your answers to various questions as you proceed, including required attachments to your application/s. Where possible, information provided during registration will also be used to pre-populate relevant fields in subsequent applications for faster and easier completion.

At a minimum, you will need the following information to complete Project Registration:

- Basic project details e.g. title, short description, study type, sponsor type/name, HREC
- Research site/s information including PI details
- Email address/es for CPI and PI/s[1]
- Project description/Research protocol
- Other project-wide/master study documents where applicable[2]

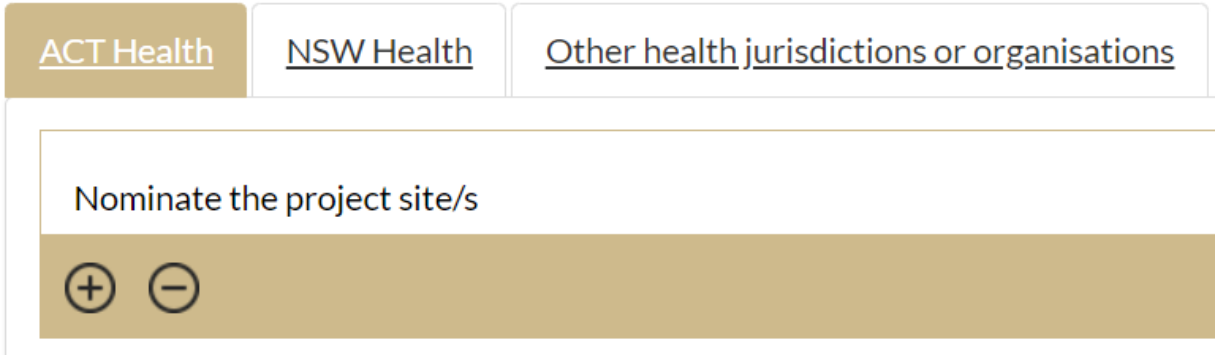
IMPORTANT NOTES:

1. Project team members listed at project registration with project roles of Coordinating Principal Investigator (CPI) and Principal Investigator (PI) must have a REGIS user profile before you will be able to complete any Project Registration and proceed to any subsequent application. Email addresses for CPI and PI/s will assist to search for their existing profile or, allow you to send a 'profile create' request during completeion of Registration. Project-level study team

Project Registration – Hints for success

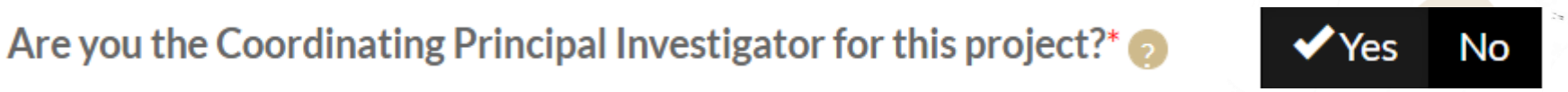
- Click on this icon for question specific help/guidance

- Add at least one NSW Site.
  Confirm sites with the Research Office managing the application/s.
  https://www.medicalresearch.nsw.gov.au/ethics-governance-contacts/



Project Registration – Hints for success

- Correctly identify the **C**oordinating **P**rincipal **I**nvestigator.



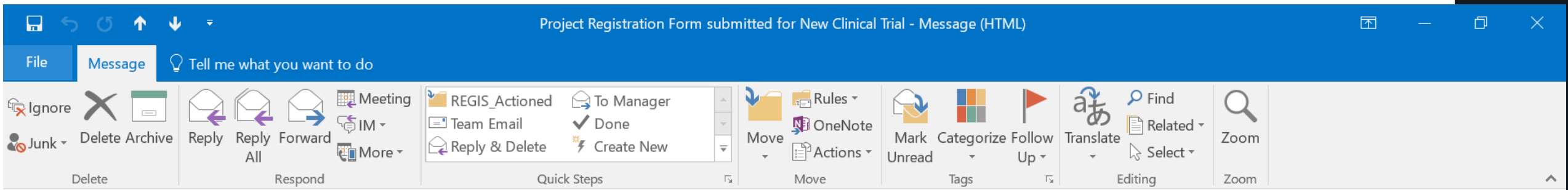
Part D: Coordinating Principal Investigator

Project Registration – Hints for success

- Upload **project wide** documents at Project Registration

- When Ethics is in REGIS/NSW HREC
  - Upload each document at PR separately

- When Ethics is in another jurisdiction (VIC, SA, QLD, WA)
  - Upload the ethics documents as a single .zip file
  - Upload the HREC approval letter separately (if available)



no_reply@regis.health.nsw.gov.au
Kylie Becker (eHealth NSW)
9:29 PM

Project Registration Form submitted for New Clinical Trial

Dear Kylie,

You have completed the project registration for your study;

Title: New Clinical Trial
Coordinating Principal Investigator: Ms Kylie Becker

PROJECT REGISTRATION IS NOT AN APPLICATION FORM

The Human Research Ethics Application (**HREA**) and/or any Site-Specific Applications (**SSA**) **will need to be completed**.

How to complete a HREA in REGIS:
If you answered '**No**' to question A1 at project registration the HREA is now available on the projects page in REGIS (click here).

Please refer to the Quick Reference Guide 'Completing an Ethics Application.'

Information completed during project registration will be pre-filled into the HREA. Please do not delete any of this information. You can add more details if you wish. The Coordinating Principal Investigator can allow anyone with a REGIS account to view or edit the HREA, but **only the Coordinating Principal Investigator can submit the HREA**. Once the HREA has been submitted, a SSA will be created for each site listed in the project registration, and emailed to the appropriate Principal Investigator/s (PIs).

How to complete an SSA in REGIS:
If you answered 'Yes' to question A1 at project registration Site Application/s are now available on the projects page in REGIS (click here)

11 Sep 2017

HREA – Hints for success

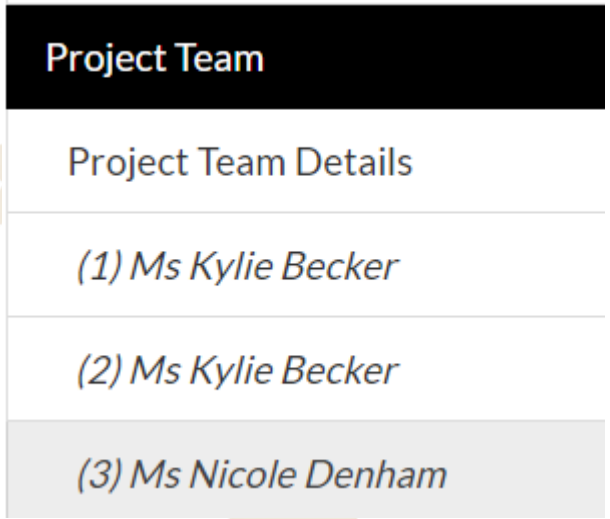
- Information completed at Project Registration will be pre-filled in the HREA.
  - Add to any free text but don't remove
  - Don't change dropdowns

Ethics Completing and Submitting the Application

- Project Team – (1) CPI as indicated at Project Registration (2) PI for site application as indicated at Project Registration
  - This may or may not be the same person

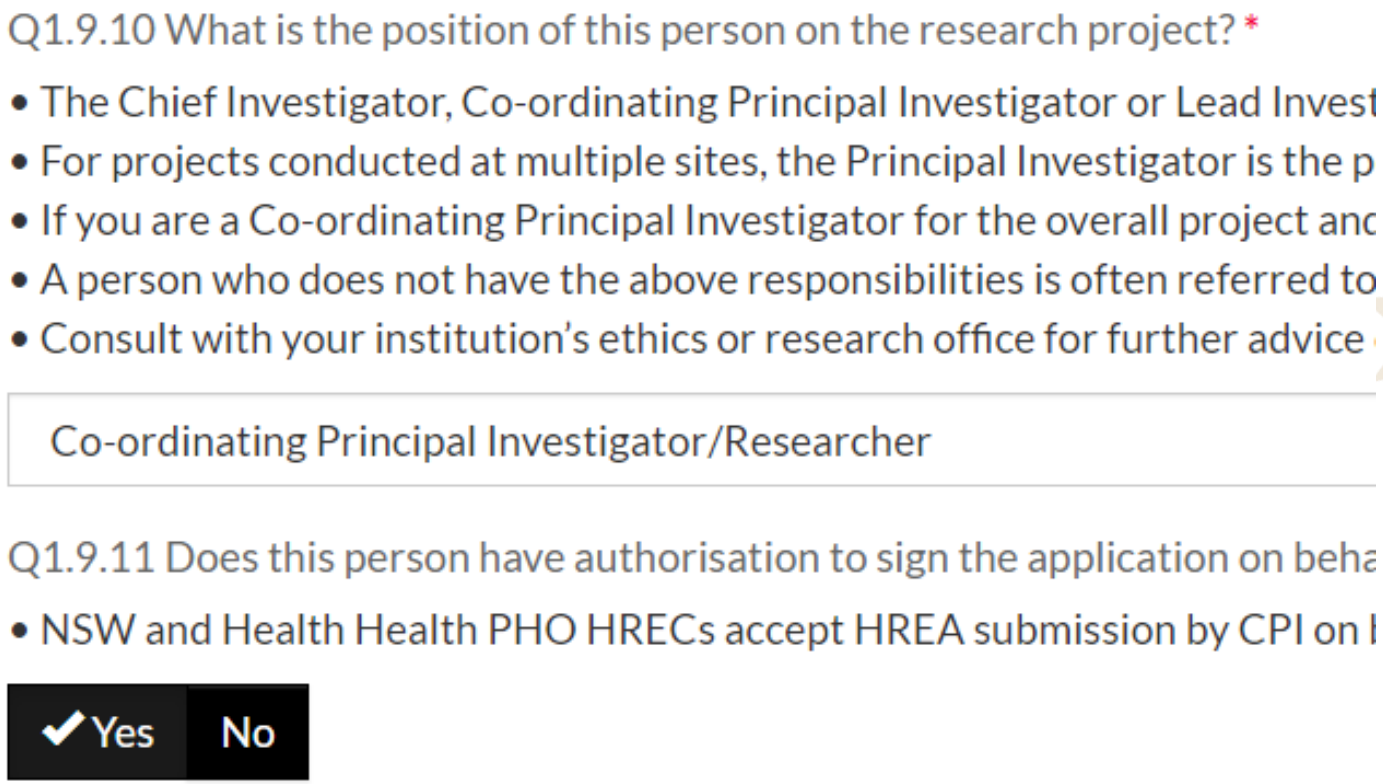
https://www.medicalresearch.nsw.gov.au/regis/

"Guidelines: Completing research team information in REGIS for NSW SSA and HREA"



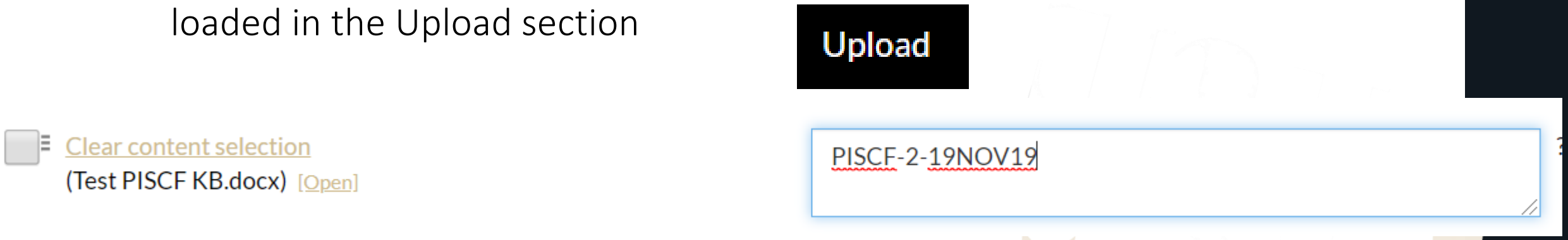
HREA – Hints for success

- Roles indicated at Project Registration are pre-filled.
  - Co-ordinating Principal Investigator/Researcher (CPI)



HREA – Hints for success

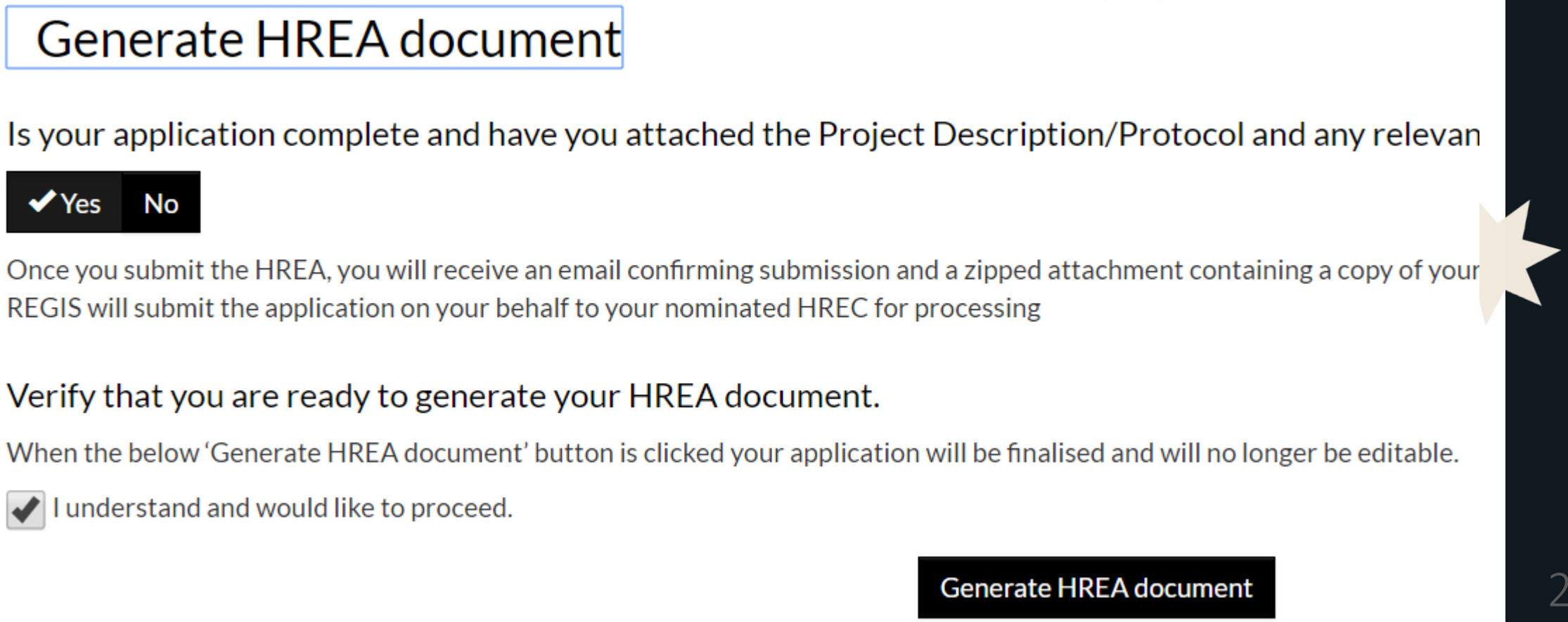
- Project wide documents uploaded at Project Registration are pre loaded in the Upload section



- To update any documents from project registration clear content selection, upload new document, update description
- Follow the description format for any new document that you upload

HREA – Hints for success

- Only the CPI will see the “Generate HREA document



Site Applications – Hints for success

- Only NSW Site Applications are create in REGIS, ACT will soon have their Site Application is REGIS.

- What's new on the NSW SSA?

https://www.medicalresearch.nsw.gov.au/regis/

Site Specific Application Part 1:
Completing Application & Requesting Head of Department Support

Site Specific Application Part 2:
Submitting Site Application after Head of Department Declaration

Site Applications – Hints for success

- Information completed at Project Registration and HREA will be pre-filled in the site application.
  - Add to any free text but don't remove
  - Don't change dropdowns

Part A: Project-Wide Information

- Part A: Project Wide Information – don't change.
  If there are areas that need correcting this could affect the ethics approval.

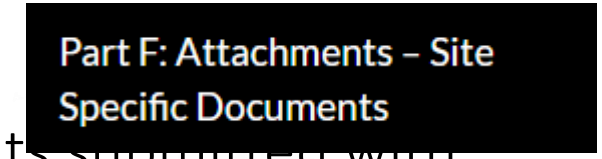
- Part C: Department and Services

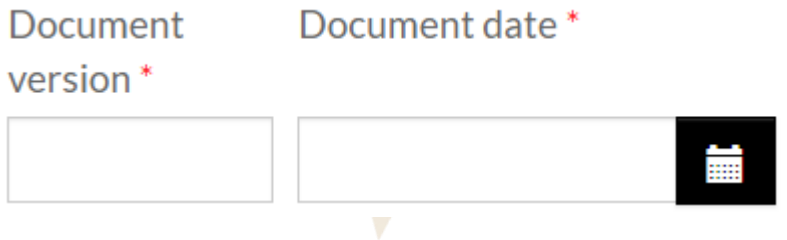
Part C: Departments and Services

A dropdown list of the most frequent Departments. Don't see the one you need? **DON'T PANIC!**
Contact the research office managing the application.
There are a number of system pathways to gaining Head of Department (HOD) sign off in REGIS.

Site Applications – Hints for success

- Part F: Attachment – Site Specific Documents
- The system includes automatically all of the documents submitted with HREA. (if no HREA in REIGS the documents uploaded at Project Registration)
- Only upload the site specific documents into the table.
- The system requires a document version and document date for all documents.
  If a document doesn't have a version or date user version "0" and the current date).





Site Applications – Hints for success

- Complete SSA for the site application to be forwarded to all Department Heads listed in the application.

- The PI and Admin contact will receive a system generated email when all HOD have made a decision.

Post approval

- A single portal for ALL NSW HRECs for post approval management.
- Amendment (general amendment, change CPI/PI, HREC extension, addition of site)
- Safety reporting
- Annual reports (milestones)

Ethics Amendment - Completing and Submitting

Ethics Amendment - Responding to an Information Request

Submitting Annual Progress or Final Report (Milestone)

- 2019 (late) site post approval management will become available.

NMA multi-centre studies

Project Registration:

- **A1** Has an application for ethics review of this project previously been submitted to a recognised HREC?
- **A5** Was/Is application being reviewed under NMA scheme?

HREC location	Site location/s	Project Registration		Result
		A1	A5	
ACT/NSW Health	ACT/NSW Health	No	NA	• HREA will be created in REGIS • NSW Sites (Project Registration, Part c) will have SSA generated after HREA submission
ACT/NSW Health	ACT/NSW Health and/or VIC/QLD/WA/SA (NMA participants)	No	NA	As-above *plus* • Minimum dataset form to be completed, site applications to be created and documents uploaded in other jurisdiction portal/s by applicant/s
VIC/QLD/WA/SA (NMA participants)	NSW	Yes	Yes	• Copies of HREA and Ethics documents uploaded during Registration • NSW Sites (Project Registration, Part c) will have SSA generated after Project Registration
Other than NMA participants	ACT/NSW Health or other locations	Yes	No	• Copies of past ethics application and all related Ethics documents uploaded during Registration • New HREA will be created in REGIS • NSW Sites (Project Registration, Part c) will have SSA generated after HREA submission

https://www.medicalresearch.nsw.gov.au/national-mutual-acceptance/

We want your feedback on how to improve the system

e. regis@health.nsw.gov.au

w. regis.health.nsw.gov.au

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https://regis.health.nsw.gov.au/your-feedback/your-feedback/