Completing Project Registration

What is project registration?

The first step in initiating your human research project in REGIS is to register it. Project registration information:
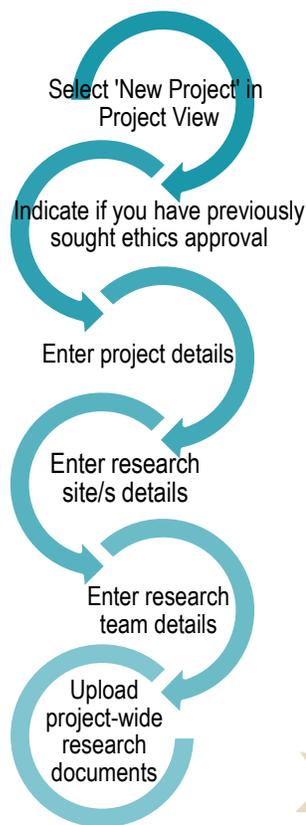
❖ will help identify if a Human Research Ethics Application (HREA) or Site Specific Assessment application (SSA), or both, are required

❖ will determine what other information you will need to provide to complete your application/s, depending on the type of project you are proposing

❖ will pre-populate fields in relevant applications for faster and easier completion.

It is important to contact your local research office and review the most recent ACT or NSW research and governance policies before registering your project. Wrongly entered information can delay the approval and authorisation process.

How does it work in REGIS?

Anyone can register a project in REGIS, including Coordinating Principal Investigators (CPIs), Principal Investigators (PIs), Sponsors, Clinical Research/Trial Coordinators, or other research project staff. In this guide, all these roles are referred to as Research Applicants.

The following diagram is an overview of the project registration process in REGIS.

Select 'New Project' in Project View

Indicate if you have previously sought ethics approval

Enter project details

Enter research site/s details

Enter research team details

Upload project-wide research documents

What information is needed?

You should have the following information ready to complete project registration:

• your REGIS user name and password
• project details – see Step 4
• research site information including PI details – see Step 4C
• email addresses for all project team members
• research protocol
• other project-wide/master study documents, where applicable.

Team members with the roles of CPI and PI must have a REGIS account before you can complete a registration.
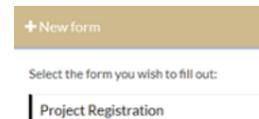
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Step 1

When you log in to REGIS, your home page will have a top right-hand gold menu bar with some icons. Click on the 'Projects' icon to go to the Project View page where you can create a new project and view all your projects

Step 2

Create a new project registration by clicking on **+ New Project** and select 'Project Registration'.

+ New form

Select the form you wish to fill out:

Project Registration

Step 3. Introduction

There are 5 parts to completing project registration that appear in the panel on the left-hand side of the screen. As you work your way through the form, questions and fields that must be completed before you can move to the next screen are marked with an asterisk *.

REMEMBER! You can save your registration at any time to return to later or to complete another section.

Navigate through the project registration process using either the left-hand side menu panel or the on screen buttons.

HINT: if questions on the page are

incomplete, use the left-hand side menu to skip an incomplete section.

Step 4: Answer the Registration questions

Part A: Past ethics application
Part A relates to the ethics application for your research project. You will be asked one question initially: *A1 Has an application for ethics review of this project previously been submitted to a recognised HREC?*

If the answer is 'No', you will proceed to Part B in the registration process. If the answer is 'Yes', you will need to answer more questions

Part B: Project details
Answer every question on this page. Note that if you are conducting a 'clinical trial', 4 additional questions (B5 – B8) will appear for you to answer.

Part C: Research site/s details

Incorrect site selection will have a major impact on the application process. Consult with the local research office if you are unsure of the sites you should list.

In Part C, list all sites where this research project will be conducted.

You can 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.

Sites will appear on the left-hand side panel under Part D, where you can add contact details for all team members.

You must enter the email address for the PI at each nominated site.

The PI is the only person who can submit the SSA in REGIS.

If the PI has an account in REGIS, their email address will be available for selection from a drop down list. Select the correct email address, and continue.

If they are not listed, you will need to invite them to register in REGIS before you can complete the registration.

Click 'Invite to Register' button to ask your colleagues to register in REGIS.

Use the plus/minus signs at the bottom to add and remove project sites.

Part D: Research team details: Coordinating Principal Investigator
The Coordinating Principal Investigator (CPI) is the person with overall responsibility for the research project at all sites.

The CPI is the only person who can submit the ethics application (HREA).

If you are the CPI, select 'yes' when asked and check that your details are visible.

If you are not the CPI, start entering the email address of the CPI to search available accounts in REGIS. If the CPI is found, select the correct email address and continue. If the CPI is not listed, you will need to invite them to register in REGIS before you can complete registration.

Part D: Site team member details
For each team member you add for a site, you will be asked to indicate their role on the project (select from the drop-down options) and whether they are a student in relation to the project (including the PI added earlier).

Part E: Research Team

Part F: Attachments to be uploaded for registration to be finalised
All project-wide/master documents relating to the research project should be uploaded before registration is finalised.

If a HREA will be generated by REGIS, you will be asked to upload the research protocol first, then all other project-wide documents required for submission with the HREA.

Site-specific documents will be uploaded with the SSA at a later stage (NSW Health sites only).

Keep your electronic filenames as short as possible and do not include any versioning or date. e.g. Protocol_REGIS or PISCF1_REGIS

E1 and E2 In the Document Title cell you should enter the title in the following format:

<Document title> <Version> <Date>
e.g. Master PISCF Patient Carer Version 11.2 Date 12 …

Step 5 Complete registration
If you are not yet ready to complete registration, you may save and return to your form at another time.

Ensure all details are correct before you complete registration. The project registration CANNOT be edited or changed after submission.

Click **Complete Registration** finalise

Once project registration has been competed:
- ❖ the project will be assigned a PID – this is an overarching Project Identifier under which ethics (ETH) and/or site governance (STE) applications will be managed
- ❖ if ethical review has not yet been sought, a HREA will be generated – see *Quick Reference Guide: Ethics Completing & submitting the Application*
- ❖ if ethics approval has been sought before project registration and a new HREA is not required, REGIS will generate SSAs for NSW sites. see *SSA Part 1 Completing the application and Requesting Head of Department Support*