



National Mutual Acceptance (NMA) in REGIS

REGIS has been developed with the intention of upholding the principles of NMA, to ensure multi-centre human research studies conducted within the participating public health jurisdictions (ACT, NSW, QLD, SA, VIC, WA) will be ethically and scientifically reviewed once by a NHMRC certified HREC. In this context, REGIS assumes that every project must have at least one associated ethics application that will either be submitted in REGIS or via another jurisdiction (NMA-only):

- ❖ projects that have already had an ethics application submitted to a HREC within a participating NMA jurisdiction external to REGIS do not require a new Human Research Ethics Application (HREA);
- ❖ project that intend to submit an ethics application to a HREC within REGIS will have a new HREA generated.

For more details regarding NMA, please refer to the relevant jurisdiction's website: [NSW](#), [VIC](#), [SA](#), [QLD](#), [ACT](#), [WA](#)

What do I need to do in REGIS?

To get started, all projects need to be registered in REGIS. Anyone can register a project in REGIS as long as they have a REGIS account. If you need help creating an account in REGIS, please view the Quick Reference Guide (QRG) *Creating and managing your REGIS Account* available [here](#).

Registration is only required once per project, all associated HREA and/or SSA created in REGIS will be associated with this Registration, so it's important to get the details right. For general guidance, please refer to the QRG: *Project registration* available [here](#).

Key questions within Project Registration that you need to be aware of specific to NMA are described in the following section.

Project Registration

Part A: Past ethics application

This section is particularly important if your application is affected by NMA.

Table 1 indicates the outcomes related to answering specific questions A1 and A5 (if required).

A1: Has an application for ethics review of this project previously been submitted to a recognised HREC?

If you will be submitting an Ethics application to an ACT or NSW Health HREC within REGIS, your answer at A1 will be 'No' - no further questions will be answered under Part A. Go to Part B. If you have submitted an ethics application to a HREC within a jurisdiction external to ACT or NSW, your answer at A1 will be 'Yes' - additional information is required to establish the status of the previous ethics application - see Figure 1. Continue answering Part A.

A2: Ethics application ID

Enter the unique identifier or reference your HREC/Research office applies to the Ethics application.

A3: Approving HREC name

Select the HREC your ethics application was submitted to from the drop-down list.

A4: HREC code

This is the ID code given to a NHMRC 'registered' or 'Certified' HREC and is pre-filled based on response to A3.

HREC location	Site location/s	Project Registration Questions:		Result
		A1	A5	
ACT Health or NSW Health	ACT Health and/or NSW Health only	No	NA	<ul style="list-style-type: none"> • HREA will be created in REGIS • NSW Sites (Project Registration, Part C) will have SSA generated after HREA submission • Check with ACT Health for SSA arrangements
ACT Health or NSW Health	ACT Health, NSW Health only and/or VIC/QLD/WA/SA (NMA participants)	No	NA	<p>As-above plus</p> <ul style="list-style-type: none"> • 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 Health	Yes	Yes	<ul style="list-style-type: none"> • Complete Ethics application and SSA as required by non-ACT/NSW Health jurisdictions • Copies of HREA and Ethics documents uploaded during Registration • NSW Sites (Project Registration, Part c) will have SSA generated after Project Registration

Table 1: Project Registration, Part A - Key questions for NMA related projects

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 *

Yes

A6 Outcome or status *

Approved
 Not approved
 Review currently underway

Figure 1 Project Registration, Part A questions relating to NMA

A5: Was/Is application being reviewed under the NMA scheme?

If you are using a NHMRC certified HREC in QLD, VIC, SA or WA that is participating in NMA, your response will be Yes - REGIS will not create a new HREA.

NOTE: if your HREC is within ACT or NSW Health, your answer should have been no at A1 and this question will not be asked.

A6 Outcome

This question appears if A5 = 'Yes'

Select the current status of the Ethics review.

A7 Date of written decision notification email/letter

This question appears based if A6 = 'Approved' or 'Not Approved'

Enter the date of the decision notification document.

Part B: Project Details

Please complete the question as asked – no details here specific to NMA. Refer to [QRG: Project registration](#) for general guidance

Part C: Research site/s

If A1='No', please name all intended sites for project activities under the relevant tab 'ACT Health', NSW Health' and/or 'Other health jurisdictions or organisations'.

If A1='Yes', please only name ACT Health and NSW Health sites under the relevant tab.

Part D and Part E

Please complete the question as asked – no details here specific to NMA. Refer to [QRG: Project registration](#) for general guidance.

Part F: Upload Attachments

As with all Project Registrations in REGIS the mandatory documents required to be uploaded will be indicated on-screen based on earlier responses.

For projects under NMA that:

Are yet to receive a decision notification

- a copy of the current version of the ethics application and all related master/project-wide documents should be uploaded as a single file (.PDF or zipped file preferred).

Have already received a decision notification

– a copy of the approved ethics application and each document listed on the Ethics Approval letter should be uploaded as a single file (.PDF or zipped file preferred).

Any other project-wide documents e.g. certificate of currency should be uploaded now too.

Site-specific documents will be uploaded later with the SSA if required.

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

Submit

Complete when all parts are ready.

What's next?

On submission of Project Registration, you will receive on-screen and emailed confirmation of Project Registration and the required applications will be generated.

SUBMISSION OF APPLICATIONS HAS NOT YET OCCURRED

Ethics and/or Site-governance application generated by REGIS will be ready for completion. Please refer to the appropriate Quick Reference Guide for further general advice [here](#).

For site governance applications involving ACT Health or other NMA jurisdictions, please refer to local information for guidance:

[VIC, SA, QLD, ACT, WA](#)

For technical assistance, contact
REGIS HELP DESK

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