About REGIS

What is REGIS?

REGIS stands for Research Ethics and Governance Information System. As the new system to replace AU-Red and Online Forms, it will help manage the ethics and governance process for human research projects conducted across NSW Health and ACT Health, once it has been fully implemented. Find out more – visit the REGIS website.

How does REGIS work?

Once you have logged into REGIS and registered your project, you will be able to complete and track your ethics (HREA) and site governance (SSA) applications through approval and site authorisation processes. These processes will be managed in the system by public health organisation research office staff. Once the project is under way, post-approval requirements such as submission of annual reports and amendments will also be managed through REGIS.

Is REGIS a secure system?

Yes. REGIS and the cloud infrastructure in which it operates are compliant with NSW Government requirements in relation to both state records and ICT security and confidentiality.

Registering and logging on

How do I access REGIS?

Access REGIS through the REGIS website on any device e.g. PC, laptop, tablet or smart phone. You just need access to the internet.

Do I need to register then log in to use REGIS?

Yes. The 'User Login' box is at the top of the home page on the REGIS website. Register to create an account, and thereafter simply log in.

The user name is your email address. If you are a research officer or work in another capacity for NSW Health or ACT Health, you must use your work email address such as jane.smith@health.nsw.gov.au, jane.smith@<mylhd>.health.nsw.gov.au or jane.smith@act.gov.au. Do not use a generic email address such as researchoffice@health.nsw.gov.au.

Research applicants outside NSW Health or ACT Health can use any legitimate email address.

You can choose your own password.

If I forget my password, will I be able to reset this myself?

Yes. You can reset your password from the 'User Login' box on the [REGIS website](#).

Managing documents

What documents will I need to upload into REGIS?

You will need to upload all documents required by the application being submitted, whether it is an ethics (HREA) or governance (site-specific (SSA)) application. REGIS will tell you what documents to upload. In most instances, you will need to upload:

- the study protocol
- information sheets
- consent forms
- surveys
- semi structured questions
- data collection tools
- research agreements and contracts
- other information as required.

Following approval or authorisation, other documents may be required to be uploaded relating to amendments, progress reports, safety notifications and other activities.

Accepted document formats for upload will include PDF (.pdf), Word (.doc, .docx) and Excel (.xlx, .xlxs)

How can HREC members gain access to review meeting items for Research Office meetings?

The easiest way is if you create your own account at regis.health.nsw.gov.au. All you need is your name and email address. You can add other contact details etc to your profile once you've got access if they opt to. By creating a login profile and then if you are added as an attendee to a meeting, you can then view and review the documents/applications attached to that meeting.

I have registered a project and now I need to update the protocol that I initially uploaded to the project. What is the simplest way to update this document?

You won't need to re-register the project, but updating the protocol will depend on where your application is up to. Probably best to discuss directly with your research office.

I'm in the process of starting an ethics application for a project that will be low to negligible risk. On the REGIS project registration section there is an area to upload project-wide documents. What sort of documents are required to be uploaded?

Please contact your research office to discuss your application. They are best placed to advise you on the required documents. You should also refer to the QRG on Project Registration for Research Applicants available [here.](#)

REGIS implementation

How is REGIS being implemented?

REGIS is being progressively rolled-out across NSW and ACT public health organisations in 2018. See Transitioning to REGIS for a list of these organisations. Research offices are at different stages of REGIS implementation so contact your local research office to find out if they are accepting applications in REGIS. A monthly REGIS Update with news about REGIS implementation is emailed to people who have registered to stay informed on the website (see the bottom of any page on the REGIS website).

What sort of applications are being accepted in REGIS?

Many research offices are now accepting applications in REGIS for projects that will be conducted at one or more public hospitals or sites in the one local health district area. Existing projects are generally still being managed through Online Forms and AU-RED. Research offices are at different stages of REGIS implementation so contact your local research office to find out if they are accepting applications in REGIS.

Is there a timeline for full REGIS implementation across NSW and the ACT?

REGIS will be fully implemented by 1st April 2019. At this point all stakeholders will need to be using REGIS.

Submitting ethics and governance applications in REGIS

What is the process for completing an ethics application (HREA) in REGIS?

The person registering the project needs to nominate the Coordinating Principal Investigator (CPI). REGIS then emails the CPI and requests them to complete and submit the ethics application.

The CPI may share the application with other users who have accounts in REGIS and give them read or write access so they can create or edit information. However, only the CPI can submit the ethics application.

For more information, read the Quick Reference Guide, Completing an ethics application (pdf) on https://regis.health.nsw.gov.au/how-to/

Will the Human Research Ethics Application (HREA) be accessible in REGIS or in Online Forms?

Once REGIS implementation is complete, any HREA to be reviewed by a NSW Health Human Research Ethics Committee (HREC) will be completed and submitted via REGIS only.

Note: there will be a transition period during which HRECs may be receiving applications via either REGIS or Online Forms.

Other public health jurisdictions (e.g. VIC, SA, QLD) will continue to receive HREAs via Online Forms unless otherwise advised.

What is the process for completing a governance or site-specific application (SSA) in REGIS?

The person registering the project needs to nominate the Principal Investigator (PI) or Principal Investigators (PIs). REGIS then emails the PI(s) and requests them to complete and submit their governance application(s).

The PI may share the application with anyone, including Sponsors, as long as they have a REGIS account. A person with shared access may be given 'read-only' or 'edit' privileges for the project application. Shared access (read-only or edit) enables the user to also track the progress of the application in REGIS.

However, **only PI(s) can submit the SSA(s)**.

For more information, read the [Quick Reference Guide, Completing a Site Specific Assessment](#) (pdf) on https://regis.health.nsw.gov.au/how-to/

Can I complete the HREA and SSA concurrently in REGIS?

REGIS does not create the SSA until the HREA has been submitted. The SSA is pre-populated with details entered on the project registration and HREA Once the SSA is complete, it can be submitted by the PI before ethics approval is received. However, **the SSA cannot be authorised until the Ethics Committee has approved the HREA**.

I am setting up a research project across several regions and not sure which HREC I apply to. What steps do I need to take?

Identify the HREC you wish to apply to and contact their Research Office to discuss the best way forward **before** continuing your application in REGIS. Contact them now to discuss your project – errors and omissions at registration do tend to have the potential to create delays down the track.

For registration, you will need to know the site/s within each Local Health District you intend to conduct the interviews. It may also be useful at this point to contact each of those LHD research offices as well to confirm the sites you wish to nominate – all contact details are available here.

You should only need to submit your ethics (HREA) application to one HREC within NSW Health, however separate site-governance (SSA) applications will be required for each site to authorise ethics approved activity. REGIS will generate each of these applications for you, pre-populate any details that are generally identified as common across each one and submit to each relevant research office. For SSAs, you will also be able to nominate the various dept. heads you require declarations of support and obtain their responses online following appropriate discussions, as required.

I am not the PI but coordinating the day-to-day business of the research itself. How is the REGIS process coordinated with the application to my local NMA-certified HREC?

Firstly, submit your local HREC application which will give you HREC project reference ID. The Principle investigator (PI) for each site you will undertake the research at within NSW Health will need to be nominated in order for the SSA to be generated for each site named. If you are not the PI, you will be able to be granted 'shared access' to complete the SSA on the PI's behalf, but they will need to submit the final application. Every PI will need their own REGIS account.

Get in contact with the Research Office at each site you are wishing to recruit participants to discuss your application and identify whether an SSA is required or not (and consequently, whether registration of your project in REGIS is required at all). The site-governance contacts within NSW Health are available here.

It is important to discuss your project with the site Research Office before proceeding – it may well help avoid in-necessary work or possible delays down the track.

Your sites though may have certain governance requirements depending on the involvement of their facilities. You may like to check these requirements with them. Research participants can be recruited from anywhere; what matters from an overall ethics and governance perspective is the 'site' at which they will participate in the clinical trial/research.

How do I add new sites to an approved project?

If the sites were part of the original ethics approval – just missed in the original project registration and SSA not created, then they should refer to the QRG 'Create a new site application'. If you need to add the site to the ethics application (i.e. it wasn't named as a potential site and wasn't part of the ethics approval), then you will need to do an amendment and can refer to the QRG 'Ethics Amendment - Completing and Submitting'. Both are on the website under the "QRGs for applicants" here.

My application has been withdrawn. Why has this happened and how do I fix it?

REGIS is set to withdraw an application if the response to a request for further information is not received within 60-days (you would have also received a message at 30-days as a reminder). When this occurs, your application is not lost – but rather the status changes to 'withdrawn' and you will no longer receive reminders to respond to the request. Open your registered project, and select "Copy Application" via the three dots. From this you can create a new application from this copy, and then follow the usual steps for submission of an application including HOD support for the updated application.

When are site team members added to a project?

It is best NOT to include them at Registration – they can be added as needed directly into the HREA once it is generated.

Are all study sites in a clinical trial required to complete the site specific assessment form regardless of whether they are a public hospital, private hospital or university?

Only NSW public health organisations (public hospitals) site applications are created in REGIS. In project registration the applicant is asked to include ALL sites that the HREC is being asked to approve. This is broken into three tabs: ACT, NSW, Other. Project registration creates a document for the HREC to clearly indicate which sites they are being asked to review on behalf of. REGIS will create a site application for each of the NSW sites selected. For further support contact your local NSW PHO research office to discuss this directly.

I have completed a HREA registration and application form for submission through REGIS, but now need to change the level of ethics approval from low/negligible risk to a higher level. Is it possible to do that once the application is completed?

If the HREC you wish to submit your application to has changed between submitting project registration and submitting the HREA, you can change the HREC selection in the HREA question

"4.4 Select the HREC or other body to which you are applying from the list below". Select the HREC you wish to submit the application to.

Can I still register a project if I don't yet know the site/s of where the research will be conducted?

Before registering your project you do need to know the site/s you are proposing to conduct the research in order to complete Part C or REGIS. The identification of the site/s and the nomination of their respective Principle Investigators (PIs) is also required for submission of the HREA to NSW Health HRECs within REGIS. The detail from Registration is uploaded to the HREA to assist and later will be used to generate SSA for NSW Health sites as required.

Quick Reference Guides to assist with the completion of each stage within REGIS are located here: https://regis.health.nsw.gov.au/how-to/

I have just completed a HREA through REGIS and it has generated an SSA application. I already have an SSA for the research project, am I able to upload this somewhere instead of going through the process again?

If you have recently submitted your HREA via REGIS, you will need to complete your SSA in REGIS. The SSA in REGIS is an updated version and will be pre-populated with much of the detail you will have already entered earlier at both Project Registration and in completing the HREA.

The other key aspect of difference to earlier SSAs for NSW sites is that REGIS will also forward your SSA to the various Heads of Dept, Supervisors etc that you require to complete online declarations of support before you complete submission of the SSA.

The sponsor is not listed in REGIS. How do I change that?

If the Sponsor is not listed, the applicant can select the 'the sponsor is not listed' and enter the correct details on the form. In time, updates to the listed sponsors will be made based on the details provided via the applications.

Progressing projects in REGIS

How will I know my application has been received by the research office?

Once ethics (HREA) or site governance (SSA) applications have been submitted via REGIS, you will receive on-screen and email notification.

Will I see the status of my application in REGIS?

Yes, you can track the progress of your application through every step of the ethics approval and site governance process. REGIS will provide status details that anyone with read or write access for that project can view, and inform the CPI, PI and other nominated contacts as appropriate, via email of status changes.

Status changes include requests for further information or amended information, and decisions made by Ethics Committees and site governance offices.

How do I check if the status has changed from registered to approved?

From your homepage you can see all Registered applications but you need to click into the application to see the status of the HREA (ethics application) or site applications (ssa). You should also be receiving system-generated emails regarding the progress of the application.

I can't find or view an application. How is this done?

Viewing depends on your level of permission. If the application is currently still In Progress, until the researcher submits the application, it will not show up for review. If the application has not yet been submitted, it technically hasn't been assigned to your HREC and therefore you can't view it. You can ask a researcher to share an application with you, and can then access it via the external portal tile and view exactly what they are seeing.

What information or notification will I receive from REGIS?

REGIS will email the CPI, PI(s) and other nominated contacts the following:

while a project application is being assessed:

- all requests for further information
- notification of status changes
- decisions from Human Research Ethics Committees (HRECs) and site governance offices

once the application has been approved or authorised:

- emailed reminders before milestones become due such as the annual progress report, or submission or ethics approval expiry dates.

Other communication between the research applicant and the research office via REGIS will occur as necessary.

Migrated projects

I submitted an ethics amendment form in REGIS, and I hoped that the status of the ethics (ETH) form would change so a site form could be created?

Submission of the amendment doesn't change the status of the ETH Project. The amendment form has been created, it just needs the receiving Research Office (SLHD – RPA) to approve the amendment for the SSA to be generated. With the approval of the site already granted, the HREC's Research Office only need to 'approve' the amendment in REGIS (i.e. it doesn't need to go back to the HREC again). The site form is automatically generated when the amendment is approved.

I am unable to create SSAs for a project for sites that have already been approved. What can I do here?

You will need to create an 'Amendment' in this instance to trigger a new SSA.

Note: this is an administrative step only, used in order to generate the SSA for a data migrated project that requires an SSA for a site already approved. Unlike a normal amendment – an 'administrative' amendment will be processed by the research office as soon as it is received and the earlier approval confirmed, it will not be reviewed by the HREC. The SSA/s will be generated on acceptance of the amendment.

The QRG *Ethics Amendment - Completing and Submitting* outlines the amendment process and is available via our website at https://regis.health.nsw.gov.au/how-to/

Applications other than for new local single-centre projects (National Mutual Acceptance)

The questions below relate to National Mutual Acceptance – click here to learn more.

What is the process for applications for multi-site research projects across state borders? For example, if a study will be completed in NSW, QLD and VIC, will a HREA need to be completed in REGIS for NSW and another HREA in Online forms for QLD and VIC?

Under National Mutual Acceptance (NMA), ethics approval granted by a certified HREC within a participating public health jurisdiction is recognised by other participating jurisdictions. Participating jurisdictions include NSW, ACT, QLD, VIC, SA and WA.

In this context, initial registration of a research project within REGIS will identify whether an ethics application (HREA) has previously been submitted to a NMA-participating Human Research Ethics Committee (HREC). If it has, completion of another HREA will not be required. However, evidence of ethics approval will be required before site authorisation can be granted. The current implementation schedule indicates REGIS will begin to accept inter-jurisdictional, multi-centre projects under NMA in late 2018.

Is REGIS used for research projects in private as well as public hospitals?

HRECs utilising REGIS may have arrangements in place to receive ethics applications from non-NSW Health organisations. REGIS will be able to accommodate those arrangements.

However, SSAs can only be generated for ACT and NSW public health organisations.

Will the CPI's/PI's current research project appear in REGIS when their site goes live?

By the close of full implementation of REGIS, all active, approved and authorised projects will be transferred into REGIS.

My project has a lead site in NSW and two participating sites in other states. Are the PI's for each participating site also required to be registered with REGIS, or can a designated site staff member be registered on the PI's behalf?

Each PI is required to have their own account - aside from being responsible for the SSA generated for sites in NSW, if amendments or other correspondence from the HREC relates to issues affecting their site/s, the PI may be cc'd by the HREC. Including the PI details at Registration also prepopulates into the subsequent HREA and SSA forms.

I am preparing an ethics submission in REGIS for a negligible risk study which has sites in NSW, ACT, VIC, WA and QLD. Can you please advise how I enter trial sites in REGIS for the sites that are not in NSW and ACT?

During project registration in REGIS you will be asked to identify the sites that the project will be undertaken – three tabs are presented: ACT Health, NSW Health and Other organisations/jurisdictions. You would enter the non-NSW/ACT Health sites in that third tab. SSA will be generated for the NSW Health sites on submission of the HREA (assuming you are

submitting ethics to an ACT or NSW Health HREC via REGIS, otherwise they will be generated on completion of the Registration).

For further guidance, please refer to the Quick Reference Guide (QRG) National Mutual Acceptance (NMA) in REGIS available here: https://regis.health.nsw.gov.au/how-to/

We also strongly encourage you to contact the Research Offices associated with the HREC you're intending to submit your ethics application and those sites you're proposing to undertake the research.

For non-NSW/ACT sites I want to be HREC-approved, must the PIs be registered in REGIS as well?

At the moment yes – this is to enable them to receive copies of ethics approvals and other correspondence as appropriate to the application (later, also for amendment acceptances and other post-approval notifications as well).

Do I need REGIS approval to conduct a research project at two interstate sites, which are not under the control of a Public Health Organisation (PHO) and which involve participants travelling from NSW?

If the site you are using is not under the control of a PHO, then it does not need a NSW SSA to be completed and submitted through REGIS.

I have an NMA HREC submission which is in QLD. As there are and will be further NSW and SA sites, what do I need to do to give these sites access to the study and allow them to produce their SSA?

Firstly, for NSW Sites:

Register Accounts in REGIS

Anyone can have a REGIS account, if you go to https://regis.health.nsw.gov.au/ select "Register" and follow the prompts. However the following people will need a REGIS account and it is advisable that these accounts are set up before you register the study.

- The Coordinating Principal Investigator (the person who will take overall responsibility of the study)
- Each NSW site Principal Investigator/s (the person/s who will take responsibility of the study at each site)
- Any Person who will need edit access to the applications.

Register the study

Anyone with a REGIS account can complete project registration.

There are two quick reference guides that I highly recommend you use to complete project registration

- Completing Project Registration – this gives you an overview of project registration.
- National Mutual Acceptance (NMA) in REGIS – this gives you specific advice on how to answer specific questions.

  REGIS supports parallel submission so you are able to register the application and create the NSW site application forms while the ethics review occurs. Get in contact with the

Research Offices for the NSW sites to confirm the site name. This will ensure the correct Heads of Department are available in the application.

Complete the site application forms

[SSA part 1: Completing the Application & Requesting Head of Department Support](#)

Help and support

What help and support is available?

To help you use REGIS:

- easy to understand step-by-step instructions are available in REGIS
- this FAQ will be continually updated on the website
- numerous [Quick Reference Guides (QRGs)](#) for research applicants have been created.

The QRGs are in PDF format and will help with all types of questions and processes, whether it be project registration, applications, document management, and others relating to decision-making and steps you need to follow.

Is there a help desk?

Yes, there is a dedicated help desk for applicants experiencing technical difficulties with REGIS, managed by F1 Solutions. Phone 1300 073 447 or email support@f1solutions.com.au. The help desk is open from Monday to Friday from 7 am to 7 pm (excluding public holidays). Your research office may also be able to help you.

What happens if REGIS goes down or is unavailable?

REGIS is a web-based platform and it is anticipated that unscheduled downtime will be rare. The service agreement with F1 Solutions requires availability 99%+ of the time between 8 am and 6 pm Monday–Friday (peak time), and 98%+ all other times (off-peak time).

Scheduled maintenance will require the system to be made unavailable from time-to-time, though this will generally only be performed in off-peak times. All REGIS users will be notified in advance on the website.

Your feedback counts

Can I provide feedback on using REGIS?

Yes, please do. All feedback from research applicants helps the REGIS team enhance and improve the system. Email regis@health.nsw.gov.au. You can also use this email address for questions that are not technical in nature.