



February 2019

REGIS readies for full implementation by 1st April

With over 1,500 applications generated to date, the Research Ethics and Governance Information System (**REGIS**) has gradually been building up steam since its initial go-live 12 months ago.

REGIS is the preferred platform for all new Ethics applications being submitted to ACT and NSW Public Health Organisations, Human Research Ethics Committees (HRECs) and associated site governance applications for NSW Health sites.

Site-governance applications (SSA) for projects approved under NMA (National Mutual Acceptance) by interstate HRECs for NSW Health Sites may now be created in REGIS. A guide to help you identify when you should use REGIS has been created – please see details in the panel below on the right.

Who needs to use REGIS?

REGIS is intended to be used by all stakeholders involved in managing ethics applications submitted to either ACT or NSW Health HRECs and/or site-governance applications for NSW Health sites.

Depending on the type, approach and scale of the proposed research, REGIS users may include Coordinating Principal Investigators (CPIs), Principal Investigators (PIs), Associate Investigators, other research team members, commercial sponsors such as pharmaceutical and biomedical companies, administrative contacts, Clinical Trial Coordinators, and Clinical Research Organisations, i.e. applicant supporters, managers and employers.

REGIS offers a centralised point for applications and post-approval/authorisation reporting and safety notifications. When possible REGIS assists researchers to meet authorisation conditions with automated reminders for annual reports and other progress-related milestones (e.g. clinical trial 'first patient in' date reporting). Support resources are available to help you interact at various stages of the system - see the blue panel below for further details.

What do I need to do?

- Start using REGIS now it's easy to login and get started
- Check our website for resources and tips in using the system
- Contact your peers and colleagues to share REGIS learnings this fosters a shared community under the health and medical research banner
- Send us <u>feedback</u> on your REGIS experience what aspects are not clear, or what type of instructional content would help you in your role?
- Visit the <u>NSW Health Medical Research</u> or the <u>ACT Health Research Ethics and</u> <u>Governance Office</u> webpages for more information about research ethics and governance within ACT and NSW.

Who to contact?

Contact your local research office/LHD for any questions about REGIS. They have been working closely with the project team for many months and can help you. You can also email us at regis@health.nsw.gov.au if you have any specific questions.

Making REGIS user-friendly

The journey began in 2017 when we began working with our IT vendor to build, test and refine the REGIS system.

Since then, we have worked on testing the system thoroughly and creating resources to help users at each stage they interact with the system.

<u>Quick Reference Guides</u> are a great reference tool for either first-time or experienced users. On-screen help also provides guidance throughout.

Research offices and their staff have done a great job in working with our project team to provide input into these guides. The feedback and consultation loop will continue as we add more news and content to our website.

REGIS will also continue to evolve over time based on user feedback and the need to respond to ethics and site governance strategic directions.

Transitioning to REGIS - where do I apply?

What exactly is a new application, and how do you apply? To get started in REGIS, **some key dates apply** - prior to 1st March, from 1st March and from 1st April 2019. Visit our <u>guide</u> for key dates and explanation.

We need these staged dates and processes as transferring from the existing system to REGIS involves legacy data, and various users at different stages of application, review and reporting.

This <u>brochure</u> provides a key explanation for first-time users of what REGIS is, and how it functions. <u>Flow charts</u> describe how an application typically works.