What is REGIS?

The Research Ethics and Governance Information System (REGIS) has been developed to assist in managing ethics and site governance of health and medical research projects across ACT and NSW Public Health Organisations (PHOs). REGIS is intended to replace AU-RED and the Online Forms portal as a single system, accessible by researchers and public health organisations administering research.

REGIS will be used to manage single and multi-site human research projects. And, as a web-based platform, it will be available 24/7 with technical support a phone call away Monday to Friday 7am-7pm.

REGIS incorporates the National Health and Medical Research Council's Human Research Ethics Application (HREA), as well as a new Site Specific Application (SSA) for site governance within NSW Health PHOs.

With the introduction of REGIS, investigators will be able to track and share visibility of their application progress online with Sponsors and other key stakeholders as needed; all NSW Health PHOs will have similar application requirements and all HREA/SSA applications will be electronic.

From 1 January 2019, all new research ethics and governance applications should be commenced in REGIS – please refer to this document for transition arrangements. If you have any questions, please contact your local Research Office *before* commencing any new application to discuss – contact details are here.

Who will use the system and how does it work?

Research applicant users of REGIS include anyone who:

- will be creating project registrations (e.g. Sponsors, administrative support team members or Clinical Trial Coordinators)
- will have the role of Coordinating Principal Investigator, Principal Investigator, or Associate Investigator
- have a need to view and/or edit access to a project.

Projects to be considered by ACT or NSW Health PHO HRECs and/or intended to be conducted within NSW Health PHO sites, will be registered in REGIS. Registration of a research project is the first step to initiate ethics and/or site governance applications after entering REGIS. Anyone, anywhere can register a project in REGIS.

In most instances once Project Registration is complete, a HREA will be generated with the CPI identified as the Owner. The CPI can share access with anyone with a REGIS account to assist in the completion of the application. However, as it is the CPI who has overall responsibility for the project, only they can submit the HREA.

Once HREA is submitted, a Site-Specific Assessment (SSA) form will be generated for each NSW Health PHO site nominated at registration. The PI nominated for each site will be the owner of the respective SSA and can share access to assist with completion. And again, it must be the PI who submits the SSA because they are recognised as having responsibility for the conduct of the project at the nominated site.

PIs will nominate relevant Heads of department in each SSA who will be asked to provide declarations of support via REGIS. **NOTE:** PIs are expected to have discussed the need for commitment of resources (personnel, budget, equipment, facilities etc) with appropriate Heads of Department prior to receiving the request for their declaration of support in REGIS.

CPIs and PIs will use REGIS to meet post approval/authorisation reporting and other research governance obligations for the duration of the research project. Emailed reminders will assist meeting due dates for scheduled reports/milestones.

To register for a REGIS user account, please visit: regis.health.nsw.gov.au

Research Office staff includes Executive Officers, Research Governance Officers, Ethics Officers, and research office administration staff. Depending on their role, research office staff will process ethics and/or site specific applications within REGIS – ensuring that each application meets the relevant criteria and facilitating approval/authorisation processes.

The Executive Officer also arranges and records the outcomes of ethics committee meetings within REGIS. The agenda, minutes and all projects under review can be seen within REGIS by those with appropriate access.

For the first time, research office staff will be able to generate extensive, real-time reporting for their site to provide greater oversight of the projects being conducted at their site.

Human Research Ethics Committee (HREC), as the decision-making body reviewing and approving research ethics applications, includes HREC Chairs and all HREC members. The committee agenda, all projects under review for the meeting and the minutes post-meeting will be visible within REGIS for all committee members.

Local site executives include PHO Chief Executives and department heads. They will authorise site governance applications within REGIS. REGIS utilises an online decision process with emailed notifications for completion. Local executives may also receive regular 'dashboard' type reports to monitor KPI and metrics performance.

NSW Health includes relevant staff in the NSW Ministry of Health. The Office for Health and Medical Research (OHMR) will provide metrics and oversee research being conducted from a NSW perspective. This information will be provided to the Deputy Secretary for Population and Public, the NSW Health Secretary, and where appropriate, the NSW Minister for Health and Mental Health.

The key application pathways in REGIS are described in *Application workflows in REGIS* available here.

What are the benefits?

REGIS will enable process and practice changes in NSW, to help offer a more seamless experience for the research applicant in obtaining ethics approval and site authorisation for their human research project. These changes will bring:

Consistency

- No matter the research location, pre-approval and post-approval requirements and processes for human research will be similar across all NSW Health PHOs.
- REGIS will hold the most up-to date information for all NSW Health locations.

Transparency

- The system will enable visibility of the application as it tracks throughout the ethics and site governance processes.
- Pre-approval and post-approval project monitoring processes will be clearly communicated with system notifications and reminders.

Efficiency

- The system is based on processes designed to enable approval/authorisation of research projects in NSW.
- Best practice benchmarks are used to monitor performance, linked to LHD Services Agreements.

For more information or to provide feedback:

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