Glossary

QUICK REFERENCE GUIDE

FOR ALL USERS

Glossary

Research Ethics and Governance Information System (REGIS) A system to assist the management of ethics and site governance of human research projects in ACT and NSW public health organisations.

Internal Portal A portal within REGIS used by research offices who manage ethics and site governance processes for human research projects in public health organisations.

ETH The letters in an application reference number indicating it relates to ethics.

External Portal A portal within REGIS used for all users except research offices in public health organisations

PID A Project Identifier or reference code given to all registered projects.

STE The letters in an application reference number indicating it relates to site assessment.

External Portal

The following terms are relevant for the REGIS external portal, used by public health organisation research offices.

CE Delegate The Chief Executive's delegate refers to a staff member who is able to make decisions on SSA applications on behalf of the CE. The delegate is determined by the PHO.

Certify When finalising the Human Research Ethics Application (HREA), the Coordinating Principle Investigator (CPI) is required to make a declaration that all information in the HREA is correct. This declaration is legally binding.

Chief Executive (CE) The executive at PHO-level responsible for the overall operations and direction of all sites and services under the remit of their PHO. Thus, they provide final authorisation to begin research at a NSW PHO when a research project complies with site governance requirements.

Coordinating Principal Investigator (CPI) The CPI is the individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators (PI's). For single centre research, the CPI and PI are synonymous.

Documents Users can upload documents in PDF (.pdf), Word (.doc, .docx) & Excel (.xls, .xlsx).

Eligibility A PHO Research Office will, upon receiving an ethics or site assessment application, assess the eligibility of the application. It is a validation process to ensure that applications meet the minimum requirements for ethical review (ethics) or to be reviewed by the Chief Executive (site assessment).

Form Within REGIS forms are used to complete actions, e.g submitting amendments or responding to requests for information.

Human Research Ethics Application (HREA) As part of the initiative to streamline ethics approval, the National Health and Medical Research Council (NHMRC) has developed this national ethics form as a replacement for the National Ethics Application Form (NEAF). The HREA aims to facilitate efficient and effective ethics review for health and medical research involving humans.

Human Research Ethics Committee (HREC) A committee constituted in line with the National Statement (NHMRC, 2007) to review, and where appropriate, approve and monitor the ethical and scientific aspects of human research.

ORCiD is a not-for-profit organisation connecting researchers through their contributions and affiliations. Each registered researcher is given a unique ID. By entering your ID in your Personal Profile in REGIS, relevant information from your ORCid account will automatically populate into the rest of your Profile.

Personal Profile Associated with your User Account is a User/Personal Profile under which you can update and manage your username/password, personal details and contact information, as well as academic/professional appointments, employment and education details.

Project Registration The first step to initiate ethics and/or site governance applications after entering REGIS. Information entered at Project Registration will help identify if either an ethics application (HREA – Human Research Ethics Application) and/or Site Specific Assessment application (SSA) is required for a project.

SITE SPECIFIC ASSESSMENT (SSA) Site Specific Assessment is the site governance process (separate to ethical review) completed at any time after the ethics application has been submitted in REGIS. The assessment helps each site decide if there are resources available to effectively conduct a research project at a nominated site. It considers risks, impacts and practices at each research location.

STAFFLINK Every employee working for NSW Health, either directly or indirectly (through a contract organisation) will have a stafflink number.

Internal Portal

The terms below relate to the REGIS internal portal, used by all other users except research offices.

APPLICATION An application sits within the Project (PID), it can be an ethics application (ETH), or a site specific application (STE). Each application will be managed within REGIS.

DASHBOARD A visual display of key data points or tasks in a process. There are several dashboards found within REGIS, e.g. on the Homepage and Custom Dashboards

DECISION A decision is the actionable outcome of a Meeting, expedited review or RGO review of an application, e.g. Approved/Authorised, Further Information, Approved Pending and Not Approved.

Decisions can be managed through the meeting process, the application directly or the Application Home Page.

HAMBURGER An icon representing a set of menu options. This icon appears regularly within REGIS, at the 'Start' button on the Homepage, and at process headings, e.g. Eligibility, Meetings, Decisions, etc.

MEETING There are three types of meetings that can be set up in REGIS:

- HREC
- Specialist Sub-committee
- Other

Meetings are a process that a Research Office may use to manage the review of New Applications, Amendments, Safety Noting and communications for the attention of a committee or group. A Research Office can invite attendees, manage meeting papers and record decisions.

A meeting will list all applications associated with it, and each application will show the meetings to which it has been assigned.

PROCESS DECISION The action that the Research Office must take to communicate the decision of a review to the CPI, PI and/or Admin Contacts. Processing a decision is a separate action to creating/updating the decision.

A Decision can be processed from a meeting or from an application.

REVIEW a Research Office may choose to set up a specialists or focused review of applications. An allocated reviewer is able view the application for review and to add comments directly via REGIS.

A completed review is available for the Research Office to manage from the Reviews Hope Page or the Application

The Review process is separate to the Meetings

TILES are a menu option normally represented by an image and words within a box. You click on the tile.

TIMELINE The project timeline shows the status updates to a project from the first registered date until current.

For technical assistance, contact
REGIS HELP DESK

support.f1solutions.com.au
1300 073 447

SHPN (OHMR) 180124