REGIS

Status Definitions

QUICK REFERENCE GUIDE

FOR ALL USERS

Status Definitions

This is an alphabetical list of the most commom status' seen in REGIS and their definitions. If a status does not appear in this list you should contact the research office managing the application to confirm the definition of the status.

	Abandoned	ETH STE	The application has been approved/authorised, but it has been determined that the project will never commence. This status in system managed and will change based off information provided in the progress report.
	Approved Approved with conditions	ETH	The HREC/Chair has approved the application and the approval email (Decision Notification) has been sent. * Refer to the approval email for conditions. The study cannot begin until the approval email is received and the site application has been authorised.
	Approved (Pending Decision Email) Approved with conditions (Pending Decision Email)	ETH	The HREC/Chair has approved the application and the research office is in the process of drafing the approval email. The study can not begin until the applicatoin is Approved AND any site authorisastions have been received.
	Approved pending further information	ETH	The HREC, EO or RGO requires information before the approval or recommendation but no changes to the application or documents. A 'More information' form is created for you to complete.
	Assigned to meeting	ETH*	The Research Office has assigned the application to a meeting. Status for information only - No further action required by the applicant.
	Authorised Authorised with Conditions	STE	The Site CE/Delegate has authorised the study for this site and the authorisation email has been sent. * Refer to the authorisation email for conditions. The study can begin at site.
	Authorised (Pending Decision Email) Authorised with Conditions (Pending Decision Email)	STE	The Site CE/Delegate has authorised the study and the research office is in the process of drafting the authorisation email. Study cannot begin at site until the authorisation email is received.
	Closed (post analysis)	ETH STE	The study has finished normally, participants are no longer being treated or examined, but the documents are not yet archived. This status in system managed and will change based off information provided in the final report.

	Completed	ETH STE	When the last participant has met the last study analysis endpoint. When reached at a single site study, this is likely the time point when data analysis can begin. When reached at the last site in a multi-site study, this is likely the time point when data analysis can begin. Participants may still be undergoing follow-up visits. It is anticipated that the final report will be submitted within 12 months. This status in system managed and will change based off information provided in the progress report
	Completed pending HOD	STE	The site application has been completed and has been sent to each of the Heads of Department listed at part C of the application. The status will change only when ALL HOD's have recorded a decison. The research office has not received this application.
	Eligible	ETH STE	Status for information only - No further action required by the applicant. A new application meets the minimum requirements to progress to review. The research office will continue to manage this application.
	Halted	STE	System managed status – created when the Site Safety form has been submitted and indicates that the HREC has Halted ethics approval.
	HOD Not Supported	STE	When one or more Head of Department has provided a response to the support request of: • Unable to support Applicant needs to view decisions. The Research Office has not received this application.
	In Progress	ETH STE	An application/form is able to be edited by the applicant. The research office cannot access an In Progress item.
	Ineligible	ETH STE	A new application does not meet the minimum requirements to progress to review. Address the details in the email.
	Information Provided	ETH STE	Applicant has provided requested information. Status for information only - No further action required by the applicant. RO will manage the application.
	Information Requested		RO has requested further information before review can be completed. Applicant action required.
	Not Approved	ETH	The HREC/Chair has not approved the study. The study cannot commence. The study cannot commence. Applicant will be required to submit a complete new application (Project Registration, ETH and STE/s) if they would like the study to be reviewed again.
	Not Approved (Pending Decision Email)		The HREC/Chair has not approved the study and the research office is in the process of drafting the notification email.
	Not Authorised	STE	The site CE/Delegate has determined the study cannot commence at the site.

			The application will be required to submit a new STE if they want the study to be reviewed.
	Not Authorised (Pending Decision Email)		The site CE/Delegate has determined the study cannot commence at the site and the research office is in the process of drafting the authorisation email.
	Pending CE	STE	The RGO has completed the site review and is currently with the CE/Delegate for the final decision to be made.
	Registered	PID	Project Registration has been completed. All studies entered into REGIS require Project Registration to be completed at the first step. Depending on the answers provided the HREA will be created then the STE/s or the STE/s only.
	Submitted	ETH STE	An application/form has been submitted to the managing research office.
	Suspended	ETH STE	The study has been temporarily stopped by the HREC, RGO or Sponsor. No research activities can continue until approval/authorisation notification is received.
	Terminated	ETH STE	After study start but before study close, discontinuation of a research project by the investigator or sponsor, where activity will not resume. Possible reasons include: Ethical, safety, financial or other grounds. Will never progress to "Complete" or "Closed (post analysis)".
	Under Review	ETH*	Status for information only - No further action required by the applicant. An application has been assigned to Review. *A research office may use the review functionality however this is not expected.
	Valid	STE	When the STE is determined as Eligible but Ethics approval has not been completed or provided. A valid application can be reviewed but the RGO cannot recommend the application to the CE/Delegate prior to Ethics approval.
	Withdrawn	ETH STE	The RO has withdrawn the application from review OR The application was in an ineligible status for over 60 days or had a request for information for over 30 days and was system withdrawn*. *System withdrawn A number of email reminders are provided prior to a system withdraw. A system withdrawn application can be reactivated in consultation and agreement of the reviewing Research Office in line with their individual policies and processes.

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.

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

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.