Status Definitions and Glossary

This is an alphabetical list of the most common statuses seen in Research GEMS 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.

HRE = Ethics application
SSA = Site application
GEM = Project identifier

Approved	HRE	The HREC has approved the application and the approval email has been sent. The study can only commence at an SA Health site once research governance authorisation has been obtained for that site, via a site specific assessment.
Approved (Pending Decision Email)	HRE	The HREC has approved the application and the research office is in the process of sending the approval email. The study can only commence once the ethics approval email is received. The study can only commence at an SA Health site once research governance authorisation has been obtained for that site, via a site specific assessment.
Approved with Conditions	HRE	The HREC has approved the application with conditions. Refer to the approval email for the conditions. The study can commence subject to the approval conditions listed in the email. The study can only commence at an SA Health site once research governance authorisation has been obtained for that site, via a site specific assessment.
Assigned to meeting	HRE	Status for information only - No action required by the applicant. The application has been assigned to a meeting, which could include a full HREC meeting, an out of session sub-committee or Chair only review.
Authorised	SSA	The site's Chief Executive/Delegate has authorised the project at that site and the authorisation email has been sent. The study can begin at the authorised site.
Authorised (Pending Decision Email)	SSA	The site's Chief Executive/Delegate has authorised the project and the research office is in the process of sending the authorisation email. The study cannot begin at the specified site until the authorisation email is received.
Authorised with Conditions	SSA	The site's Chief Executive/Delegate has authorised the project with conditions. Refer to the authorisation email for the conditions. The study cannot begin at the specified site until the authorisation email is received and the conditions actioned, where necessary.
Closed	HRE & SSA	The project has been finalised. Participant activities have concluded and all reports and publications have been finalised. No new outputs will be developed and the relevant datasets have been archived.

Completed pending HOD	SSA	The site application has been submitted to each of the Heads of Department (HOD) listed at part C of the SSA application. The status will change only when ALL HOD's have recorded a decision. The research office has NOT received this application.
Completed	HRE & SSA	When the last participant has met the last study analysis endpoint and/or all data collection is complete. Approved analyses have been finalised although the publication process may not be complete. No new analyses will be initiated using study data without additional approvals
Eligible	HRE & SSA	Status for information only - No action required by the applicant. The application meets the minimum requirements to progress to review. The research office will continue to manage this application.
HOD Not Supported	SSA	When one or more Heads of Department (HOD) has provided a response that does not support the project. The research office will communicate with the applicant to advise the corrective
In progress	HRE & SSA	An application or form is able to be edited and is sitting with the researcher to action. The research office cannot access an In Progress item.
Ineligible	HRE & SSA	The new application does not meet the minimum requirements to progress to review. Details supplied via email will need to be addressed to progress this application.
Information provided	HRE & SSA	Status for information only - No action required by the applicant. The research office will manage the application.
Not Approved	HRE	The HREC has not approved the study. The study cannot commence.
Not Authorised	SSA	The site's Chief Executive/Delegate has not authorised the study at the specified site. The study cannot commence at the site.
Registered	GEM	Project Registration has been completed and submitted. Depending on the answers provided, the HREA and/ or SSA templates will be generated ready for completion.
Submitted	HRE & SSA	An application/form has been submitted to the managing research office.
Suspended	HRE & SSA	The study has been temporarily stopped by the HREC, Research Governance Officer or sponsor. No research activities can continue until an approval/authorisation notification is received.
Terminated	HRE & SSA	After ethics approval 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 Completed or Closed (final report).
Under Review	HRE	Status for information only - No action required by the applicant. An application has been assigned to Review.
Valid	SSA	When the SSA is determined as Eligible but ethics approval has not been received or provided. A valid application can be reviewed by the RGO but cannot be recommend to the CE/Delegate prior to ethics approval.
Withdrawn	HRE & SSA	The researcher has withdrawn the application from review.

Glossary

External Portal A portal within Research GEMS used for all users except research offices.

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

HRE The identifying application reference number indicating an ethics application.

Internal Portal A portal within Research GEMS used by the SA Health research offices who manage ethics and site governance processes for human research projects.

Research GEMS The system to assist the management of ethics and site governance of human research projects in South Australia.

SSA The identifying application reference number indicating a site specific assessment application.

External Portal

The following terms are relevant for the Research GEMS external portal, used by all other users except 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 local health network.

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 the local health network, responsible for the overall operations and direction of all sites and services within their organisation. They provide final authorisation to begin research at their SA Health site 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 Files created, managed and uploaded by a user. Users can upload documents in PDF (.pdf), Word (.doc, .docx) & Excel (.xls, .xlsx).

Eligibility A Research Office will, upon receiving an ethics or SSA 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 Research GEMS 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. The HREA facilitates 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, 2023) 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 Research GEMS, 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. 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 Assessments are the site governance process (separate to ethical review) completed at any time after project registration. The assessment helps each site decide if there are resources and support available to effectively conduct a research project at a nominated site. It considers risks, impacts and practices at each research location.

Internal Portal

The terms below relate to the Research GEMS internal portal, used by SA Health research offices.

APPLICATION An application sits within the Project (GEM), it can be an ethics application (HRE), or a site specific application (SSA). Each application will be managed within Research GEMS.

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.

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

- 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 Research GEMS.

A completed review is available for the Research Office to manage from the Reviews Home 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. They display groups of projects, as setup by the user.

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