

# Applications and projects defined

#### Introduction

The Research GEMS system uses a lifecycle structure to manage the phases of your project, beginning with a project registration.

This document aims to provide some background information on the forms that are created in the phases of your study.

### What is a project registration?

The first step in initiating an ethics (HRE) and/or site-specific assessment (SSA) is to register your project in GEMS. This form captures the core content of your study to identify if a human research ethics application (HREA) and/or SSA application/s is required and sets up the appropriate structure of your study in GEMS.

The form will give you the opportunity to provide details of the coordinating principal investigator (CPI) for HREA and the principal investigator (PI) for all SSA application/s. Administration contacts can also be added to assist in the completion, submission, and ongoing management of the study.

While you can update team members throughout the lifecycle of the study, it is best if you enter the correct contacts for your study in the initial application phase.

If team members have completed their GEMS profile, key information such as their position and contact information will be prepopulated in the HREA and SSA application/s upon creation.

# What is an application?

The application phase in GEMS hosts all the pre-approval activities involved in the approval process for your HREA and/or SSA application/s. This can include application eligibility checks, reviews, and meeting records.

Upon submission of the project registration, the system will generate a HREA if ethics approval is being sought through a SA Health Human Research Ethics Committee (HREC), along with SSA All post approval related activities such application/s for each site where the study may take place in South Australia.

Further information on National Mutual Acceptance applications can be found here.

The HREA and SSA application forms will allow you to provide all relevant information required during the application's approval stage of the study.

# What is a project?

Upon approval of the HREA or authorisation of a SSA application, the system generates a project for your study.

Projects within GEMS are created to separate the processing requirements between PRE-approval and POST approval activities and forms for your study.

as amendments, progress reports and milestones are found and submitted via the project record of your study.

Each HREA and SSA application/s will have their own project, allowing for specific and direct reporting.

The system's study phases are illustrated below.

