Sharing access to applications and projects

Introduction

Depending on your role in an application or project, you may have access to view, edit or submit applications and forms.

An application or project can be shared with anyone with a Research GEMS account. This can include people that are not part of the research team e.g. Sponsors, Coordinators, etc.

Ownership and Access

Project Registration

Anyone with a GEMS account can create, share and submit a Project Registration.

The creator is the **Owner** of the Project Registration and will automatically have Editor rights to the associated ethics and/or site applications.

Ethics (HREA)

The Coordinating Principal Investigator (CPI) listed in the Project Registration is automatically the **Owner** of the ethics application. The CPI has overall responsibility for the management of the study.

Site (SSA)

The Principal Investigator (PI) listed in the Project Registration is automatically the **Owner** of that site application. The PI has overall responsibility for the management of the study at the listed site.

The CPI also has **Edit** access to any site application/s and is able to share the application further.

Administration Role
Anyone added as an Administrator is copied into all email communications from Research GEMS. This role can be applied in any of the above forms.

Sharing Rules

A maximum of two users may be allocated **Submit** rights for ethics and each site application.

Clinical Trial applications allow for an additional Associate Investigator (AI) to be included with submit rights.

GEMS will generate emails to the CPI for ethics and PI for sites to approve this level of submit access. The user guide for these approvals can be found [here](#).

Important: while this allows additional staff to assist with the management of studies in GEMS, the responsibility of the study remains with the CPI and PI's respectively.

Access Levels - Definitions

Share with View Access
User can only view the application and forms, but is not able to make changes.

Share with Edit Access
User can view and edit the application and forms.

Share with Edit and Submit Access (Owner +2 delegates)
User can view and edit the application and forms. The user will also be able to submit the application and forms on behalf of the CPI or PI.

How the Share Function works

The Share Function allows you to quickly share an application or project with team members and is accessible from all forms within GEMS.

To access this feature, look for any of the following buttons:
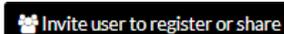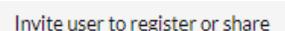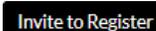
After clicking any of these buttons, the share window will be displayed.
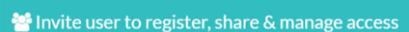
To add a user:
Click the "**+ Add another user**" button, then enter the email address of the person who is being shared access.

If the email address **is not** recognised as a registered GEMS account, an invitation to register email will be sent:

If the email address **is** recognised as a registered GEMS account, a notification will be sent to the added user that access has been shared:

Select the level of access for the user and click **Save and Send** to complete the invitation to share.

To resend an invitation or notification:
Tick the check box and click the **Save and Send** button.

To remove a user:
Click the [trash] button

How to share:
Project Registration form

This can only occur **before** the Project Registration form is submitted and registered.

Use the **Invite to Register** button on these pages to access the Share Function:

- ❖ **Part C:** Research Site/s
- ❖ **Part D:** Coordinating Principal Investigator

How to share:
HREA/SSA Forms from the Project Registration form

In addition to sharing the Project Registration, you can also share access to the HREA and/or SSA form/s from this initial form.

Enter the details of additional team members in **Part C and D** of the Project Registration.

If delegation for submit access on behalf of the CPI and/or PI were selected for team members, and the person submitting the project registration is not the CPI or PI, an approval email will be sent to the CPI and/or PI respectively to approve the delegate request.

It is recommended to set these team members up in Project Registration from the start if possible.

For further information on completing the Project Registration, click here.

How to share:
Ethics (HREA) form

Once the HREA has been generated, details on how to provide access from within the form can be found below.

Part 1
Access to view or edit HREA only
Use the Share Function by clicking on the **Invite user to register or share** button from the top right hand corner of any page.

Part 2
Ongoing access to view or edit the HREA *(includes post approval access)*
Complete the instructions in Part 1.

The user must also be added into the **Project Team** tab of the HREA form.

Optional: to receive emails related to this application from GEMS, answer **Yes** to *Q1.9.5 Is this person the contact person for this application?*

Part 3
Ongoing access to submit HREA forms *(includes post approval access)*
Complete the instructions in Part 1 & 2.

Answer **Yes** to: *Q1.9.11 - Does this person have authorisation to sign the application on behalf of all members of the research team?*

Important: the email to the CPI or PI to approve submit access is not generated until the HREA has been submitted.

How to share:
Site (SSA) form

Once the SSA has been generated, details on how to provide access from within the form can be found below.

Part 1
Access to view or edit SSA only
Use the Share Function by clicking on the **Invite user to register or share** button from the top right hand corner of any page.

Part 2
Ongoing access to view or edit the SSA *(includes post authorisation access)*
Complete the instructions in Part 1.

The user must also be added into the **Part B: Site Team** tab of the SSA form.

Answer **Yes** to **B7** to provide an Administration contact, and enter the team member's details.

Part 3
Ongoing access to submit SSA forms *(includes post authorisation access)*
Complete the instructions in Part 1 & 2.

Answer **Yes** to providing authorisation to submit the SSA and other related forms.

Optional
For Clinical Trials, an Associate Investigator may be listed in question B8, with view, edit or submit rights.

Important: the email to the CPI or PI to approve submit access will not be generated until the SSA has been submitted.

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How to Share:
Post Approval – Ethics (HREA) project

Once Ethics has been approved, changes to team members can be made via the ethics amendment form.

For further information on how to complete and submit an ethics amendment, click here.

Note: Sharing rules apply to both application and post-approval project forms. If you attempt to add more than the maximum number of delegates that the system allows for submit access, an error message will prompt you to review your selection.

Maximum number of delegates has been reached. Please contact the relevant Research Office.

How to Share:
Post Authorisation – Site (SSA) project

Once an SSA has been authorised, changes to site investigators and team members can be made via the site amendment form.

For further information on how to complete and submit a site amendment, click here.

Note:
Sharing rules apply to both application and post-approval project forms. If you attempt to add more than the maximum number of delegates that the system allows for submit access, an error message will prompt you to review your selection.

Maximum number of delegates has been reached. Please contact the relevant Research Office.

How to Share:
From the home screen – Applications and Projects

Step 1
Locate your application or project
When you log in to GEMS, your home page should show your top 5 projects. If you can see the project here, open it by clicking on the project identifier or the title.

If the project is not listed in your top 5 projects, click the 'Projects' icon, followed by the title or identifer to be taken to the Project Details page.

Projects

Step 2
The project title will appear at the top of the screen and you will see the ethics and/or associated site applications.

Click within the line of the Ethics/Site Application you wish to share access.

Step 3
Click the **Invite user to register or share application** *(pre approval)* **or project** *(post approval)* button.

Invite user to register or share application

Invite user to register or share project

Step 4
This will open the Share Function for you to add users and their access.

Form Names and System Access Levels required

Research GEMS – Form Names	Who Can Submit – Required Access Level
Project Registration	All users
HREA	Submitters and Owners only
SSA	Submitters and Owners only
Notification of an amendment to a research study	Submitters and Owners only
Site Amendment	Submitters and Owners only
Protocol Deviation form	Submitters and Owners only
Annual/Final Progress Report	Submitters and Owners only
Reporting Local Safety Events to the Institution	Submitters and Owners only
Safety reporting form	Submitters and Owners only
Site Annual/Final Progress Report	Submitters and Owners only
Serious Breach Report form	Editors, Submitters and Owners
Upload Final Ethics Approval	Editors, Submitters and Owners
40-day Progress Report – Clinical Trial	Editors, Submitters and Owners
Certificate of Currency	Editors, Submitters and Owners
More information required	Editors, Submitters and Owners
More information required – RGO approval	Editors, Submitters and Owners
More information required – SSA	Editors, Submitters and Owners
New site form	Editors, Submitters and Owners
Clinical Trial Data Collection	Editors, Submitters and Owners
First Patient In	Editors, Submitters and Owners