

Processing Migrated Applications

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Processing Migrated Applications

1. Purpose

The purpose of this guide is to assist Executive Officers (EO) and Research Governance Officers (RGO) in processing applications migrated to Research GEMS.

This guide covers:

1. Processing in-flight ethics applications
2. Processing in-flight site applications
3. Addition of new sites through an 'administrative amendment'
4. Processing post-approval monitoring

The Research GEMS training manual is referenced throughout this guide.

2. Background

Applications migrated to Research GEMS do not contain the same information as an application that is submitted in GEMS, therefore some extra steps are required in their processing.

All migrated applications and projects contain the 'Migrated' tag. These tags will be displayed on various screens to let the user know they are working with a record migrated from the old system.

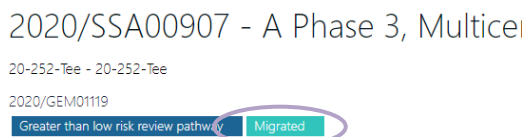


Figure 1: Migrated tag attached to migrated project

For migrated applications, special attention is required when:

- creating reviews for an application
- adding the application to a meeting
- recording decisions
- editing emails that will be sent to the researcher
- checking the project post approval/authorisation

3. Processing in-flight Ethics applications

3.1 Checking the CPI

Before processing an in-flight application, the Executive Officer will need to ensure that a CPI is recorded against the application. If a CPI is not recorded against the application, it will not process correctly and the Ethics project will not be created. To check whether a CPI exists for an in-flight application, open the application in the Application Viewer, go to the Summary screen and look for a name against the 'Coordinating Principal Investigator'.

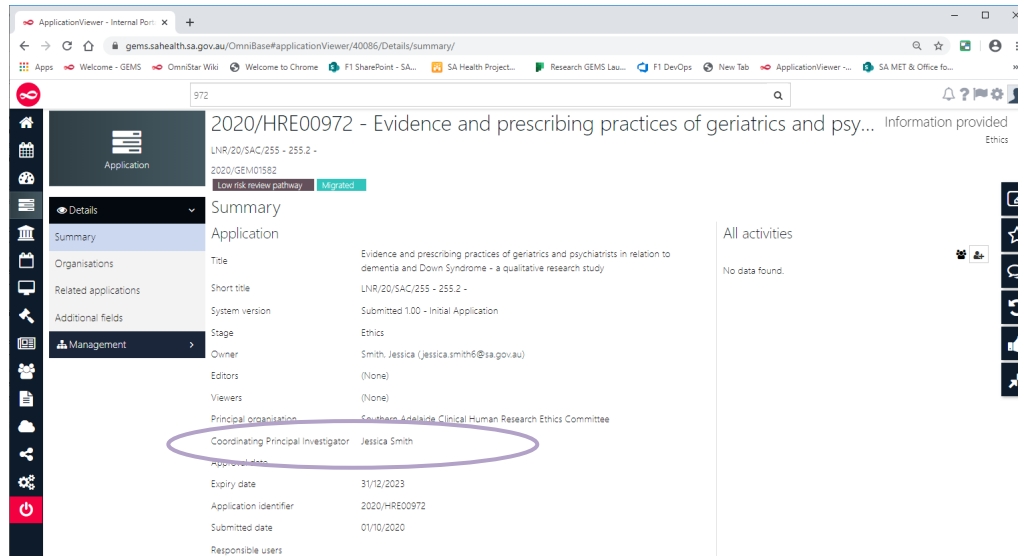


Figure 1: Application Contacts

Please contact the Research GEMS team if the application you are processing is missing a 'Coordinating Principal Investigator'.

3.2 Reviewing Eligibility

In-flight applications without a recorded eligibility date will be required to undergo an eligibility check before proceeding to a review and decision. To check if an eligibility date has been recorded against an in-flight application, select 'Status' and check for a status of 'Eligible' (see Figure 2).

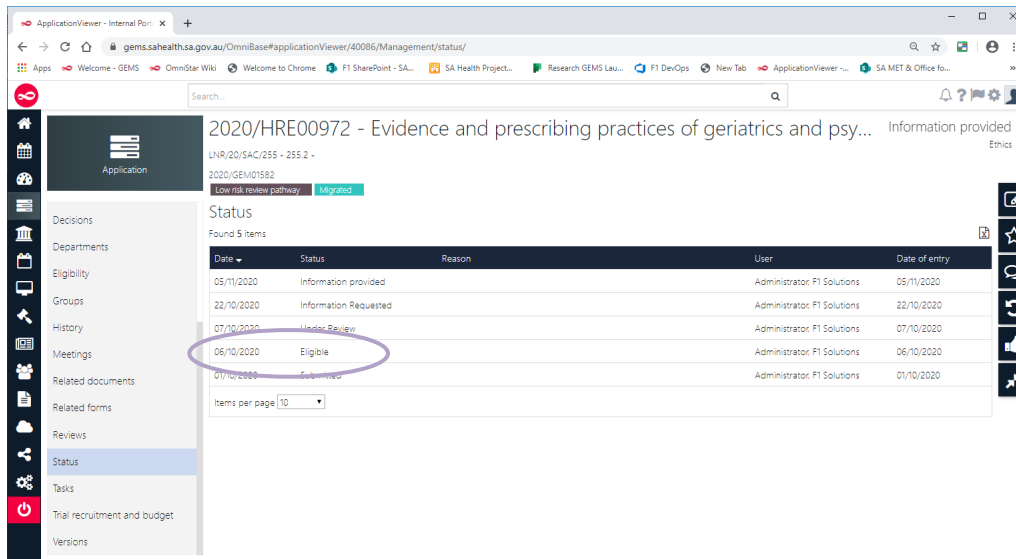


Figure 2: Application Eligibility

If an Eligible status **does not exist**, complete the Eligibility check as per section 2.2 of the training manual.

If the CPI has already been notified that their application is eligible, you can skip sending the eligibility email from GEMS by toggling off the 'Send Email' option on step 5 of the eligibility check.

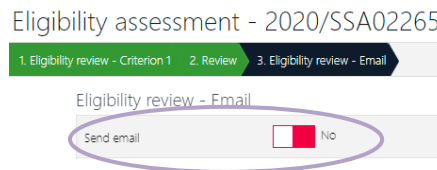


Figure 3: Eligibility check email

3.3 Uploading application documentation

The migration of applications did not bring across supporting documents. Before processing an in-flight application, the application documents need to be manually uploaded. The upload is performed on the Application Viewer Related Documents screen. To access the screen, display the application in the Application Viewer and select Related Documents in the left menu (see Figure 4)

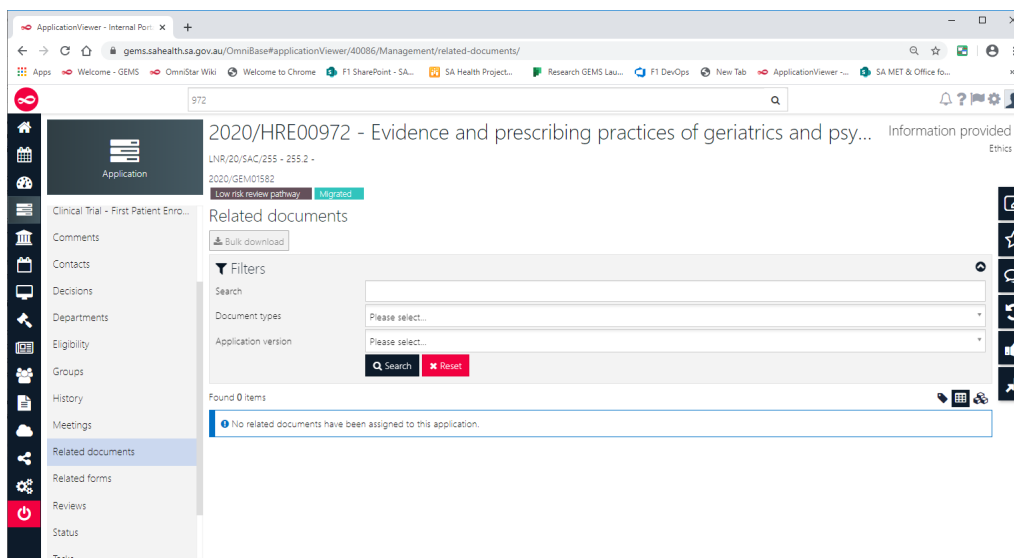


Figure 4: Application related documents

To add documents to an application:

1. Select the Edit icon in the top right. Then click on the '+ Add document' button
2. Either drag the files into the 'Click or drop your files here' area or click to the select files
3. After files have been uploaded, the document type needs to be selected
4. Select the appropriate document type from the drop down list for each file then click the Save button
5. Ensure the documents are shared with the related sites (in related projects/applications) and the research project team (in Research GEMS) if appropriate. Note that some files (such as briefings) should **not** be shared. Ensure the files are shared as necessary.

Check whether the file is shared by hovering over the first two icons next to the file.



Figure 5: File sharing icons

6. If the sharing is incorrect, click on the icon to change the setting

3.4 Creating an application review

The Executive Officer should check that the required supporting documents are available to HREC members when adding migrated applications to a review. If any documents are missing, they can be added using the instructions in the preceding section.

Reviews can be created as per the process described in section 2.3 in the training guide.

3.5 Add application to a future meeting

The Executive Officer should check that the required supporting documents are available to HREC members when adding migrated reviewed applications to a meeting. If any documents are missing, they can be added using the instructions in the preceding section.

Meetings can be created as per the process described in section 2.4 of the training guide.

3.6 Adding an application to a previous meeting

In order to record the outcome of an in-flight application that has been to a meeting since the data migration sheets were provided, the Executive Officer will need to create a meeting in GEMS. Meetings can be created as per the process described in section 2.4 of the training guide. When creating the meeting, use the correct submission closing date and meeting dates, as they are utilised in the metrics reporting.

Care should be taken when adding members to a meeting as they will be notified of the meeting. For this reason, it is suggested to create a “shell” meeting, by excluding members from the meeting and adding applications only.

3.7 Recording an application decision

After adding the application to a meeting, the Executive Officer will need to record the decision outcome as per section 2.5.3 in the training guide

Note – the decision type ‘Decision pending further information’ is unable to be used for migrated in-flight applications. If further information is required, it should be sought via email and uploaded to the application in the ‘Related Documents’ section. In this case the status of the application should also be updated to ‘Information Requested’ to stop the clock. Once the information has been provided by the researcher the status can then be updated to ‘Information Provided’ to start the clock again.

3.8 Sending an application decision notification

If the CPI has not been informed of the application decision, you can send the decision email as per section 2.5.5 of the training guide whilst noting the following information.

Research GEMS presents users with email templates appropriate to the decision being made. These emails may contain links to applications and may request the researcher to update applications and add or amend supporting documents.

Before sending the emails, the Executive Officer should review the email as follows:

- If the email contains links to access application documentation, that all documentation has been uploaded
- Check and update application decision date and expiry date
- Check for and update broken tokens which will appear in curly brackets, as the required data may not be available for the in-flight application

If the CPI has already been notified of the application decision, you can skip sending the decision email from GEMS by replacing the CPI email address with your own email address in the To: field (see Figure 6). Ensure the original decision email or letter has been uploaded to ‘Related documents’ if this is the case.

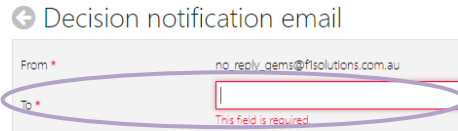


Figure 6: Eligibility check email

3.9 Updating the application and project approval date and expiry date

The application and project approval and expiry date may need to be updated for applications processed in GEMS. After recording the decision, check the 'Summary' page on the application AND project to ensure the approval and expiry date are correct.

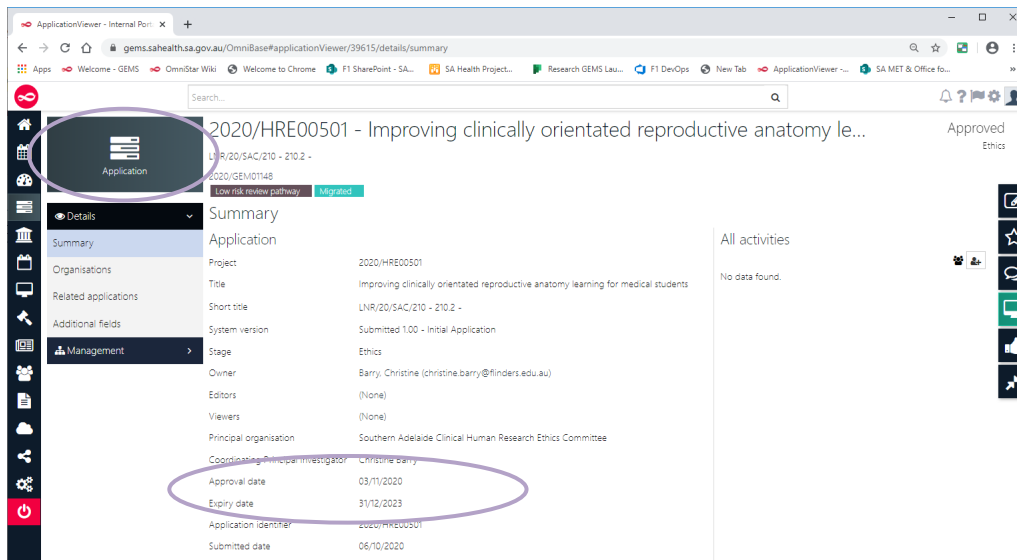


Figure 7: Approved application summary

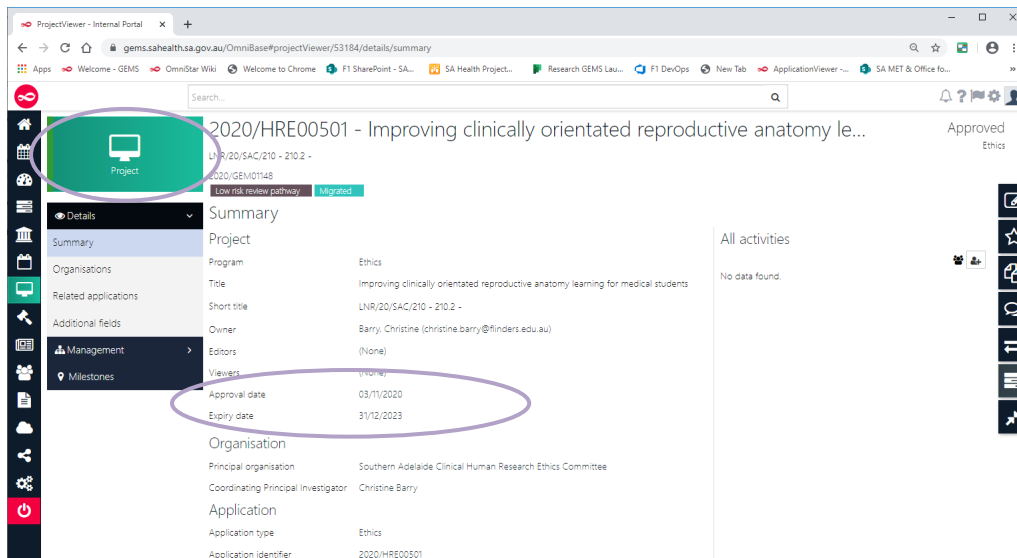


Figure 8: Approved project summary

If the approval or expiry dates are incorrect, update them on both the application and ethics project:

1. On the application, click on the 'Edit' icon on the right hand side
2. Edit the approval and expiry date fields and click Save
3. On the project, click on the 'Edit' icon on the right hand side
4. Click on the 'Change project start date' button
5. Set the approval date and click Save
6. If required, edit the expiry date then click the Save icon on the right hand side

3.10 Checking the project

After processing the application decision, the Executive Officer should check the project as per section 2.5.6 in the training guide.

4. Processing in-flight Site applications

4.1 Checking the CPI and PI

Before processing an in-flight application, the Research Governance Officer will need to ensure that a CPI and PI are recorded against the application. If a CPI or PI is not recorded against the application, it will not process correctly and the Site project will not be created. To check whether a CPI and PI exists for an in-flight application, open the application in the Application Viewer, go to the Summary screen and look for a name against the 'Owner' (PI) and 'Coordinating Principal Investigator'.

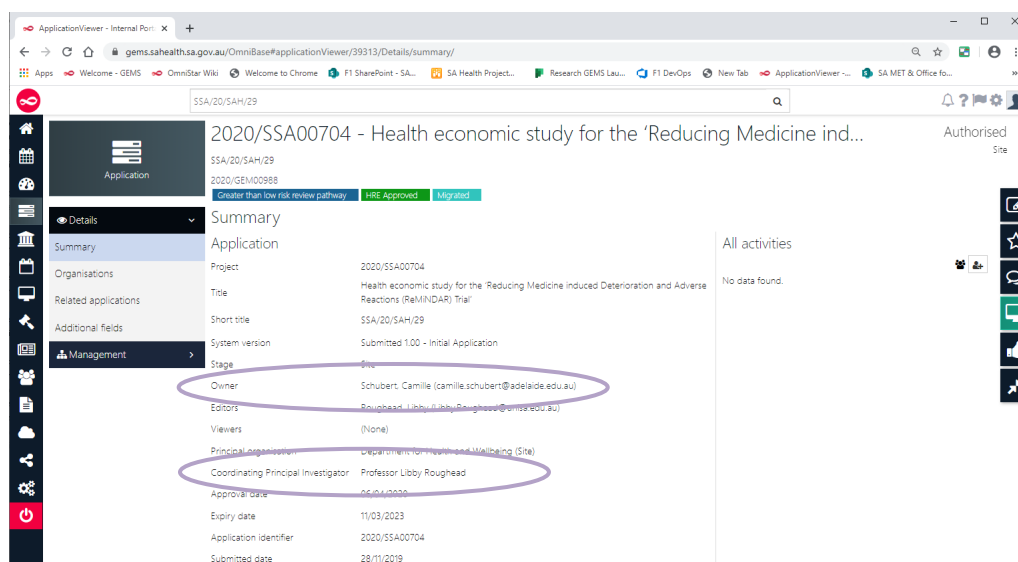


Figure 9: Application Contacts

Please contact the Research GEMS team if the application you are processing is missing a 'Owner' (PI) and/or 'Coordinating Principal Investigator'.

4.2 Reviewing Eligibility

In-flight applications that do not have a recorded eligibility date will be required to undergo an eligibility check before proceeding to a review and decision. To check if an eligibility date has been recorded against an in-flight application, select Status and check for a Status of 'Eligible'.

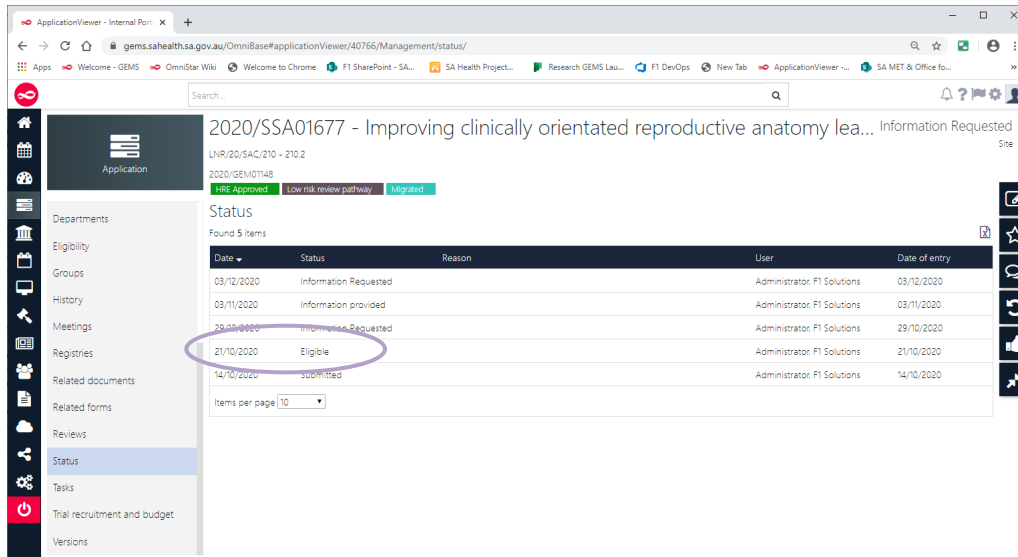


Figure 10: Application Eligibility

If an Eligible status **does not exist**, complete the Eligibility check as per section 4.2 of the training manual.

If the PI has been notified that their application is eligible, you can skip sending the eligibility email from GEMS by toggling off the 'Send Email' option on step 5 of the eligibility check.

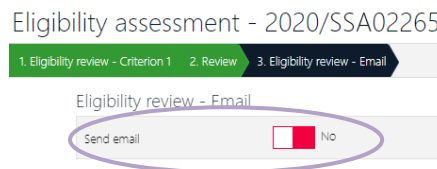


Figure 11: Eligibility check email

4.3 Uploading application documentation

The migration of applications did not bring across supporting documents. Before processing an in-flight application, the application documents need to be manually uploaded. The upload is performed on the Application Viewer Related Documents screen (see Figure 12). To access the screen, display the application in the Application Viewer and select Related Documents in the left menu.

If the related ethics application exists in GEMS, the Executive Officer should upload the application documents. If this has not occurred, please liaise with the appropriate Research Office to have them added. If the ethics application has been approved by an interstate NMA HREC, the Research Governance Officer will need to upload the application and any other related documents.

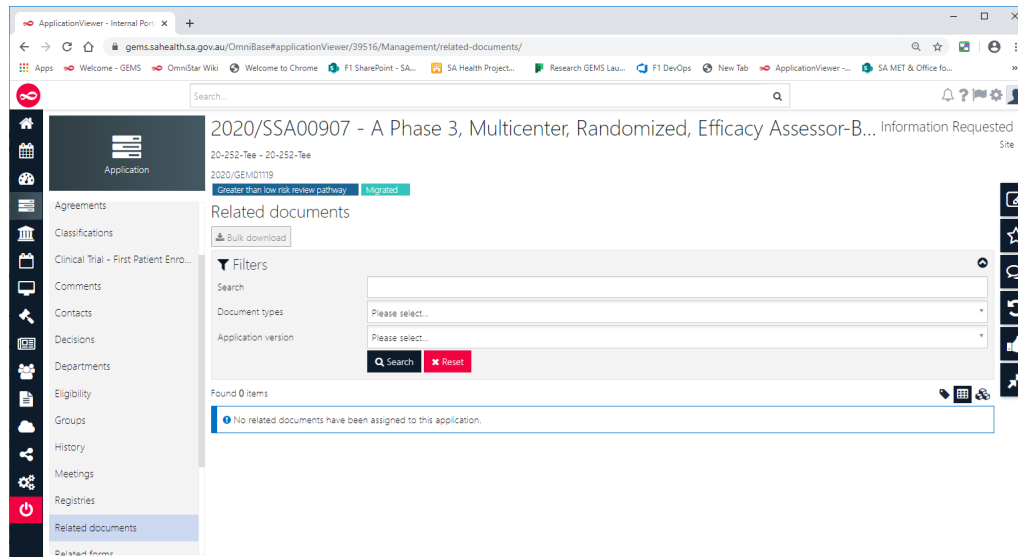


Figure 12: Application related documents

To add documents to an application:

1. Select the Edit icon in the top right. Then click on the '+ Add document' button
2. Either drag the files into the 'Click or drop your files here' area or click to the select files
3. After files have been uploaded, the document type needs to be selected
4. Select the appropriate document type from the drop down list for each file then click the Save button
5. Ensure the documents are shared with the related sites (in related projects/applications) and the research project team (in Research GEMS) if appropriate. Note that some files (such as briefings) should **not** be shared. Ensure the files are shared as necessary

Check whether the file is shared by hovering over the first two icons next to the file.



Figure 13: File sharing icons

6. If the sharing is incorrect, click on the icon to change the setting

4.4 Recording an application decision

Before a RGO decision can be made the associated Ethics application needs to have an outcome of 'Approved' or 'Approved with conditions'. If the associated ethics application does not exist in GEMS, the ethics decision letter will need to be uploaded to the 'Related Documents' section with the document type 'Ethics application decision notification' before a RGO decision can be created.

To record a decision against a governance application, the Research Governance Officer will need to manually create the 'RGO Decision' against the application (see Figure 14). To add the RGO decision:

1. Display the application in the Application Viewer and select Decisions the left menu
2. Click the Edit icon on the right hand side
3. Click 'Add Decisions'

4. Set the due date of the decision
5. Select the decision type as 'Recommendation by RGO'
6. Select the user performing the decision and click Save

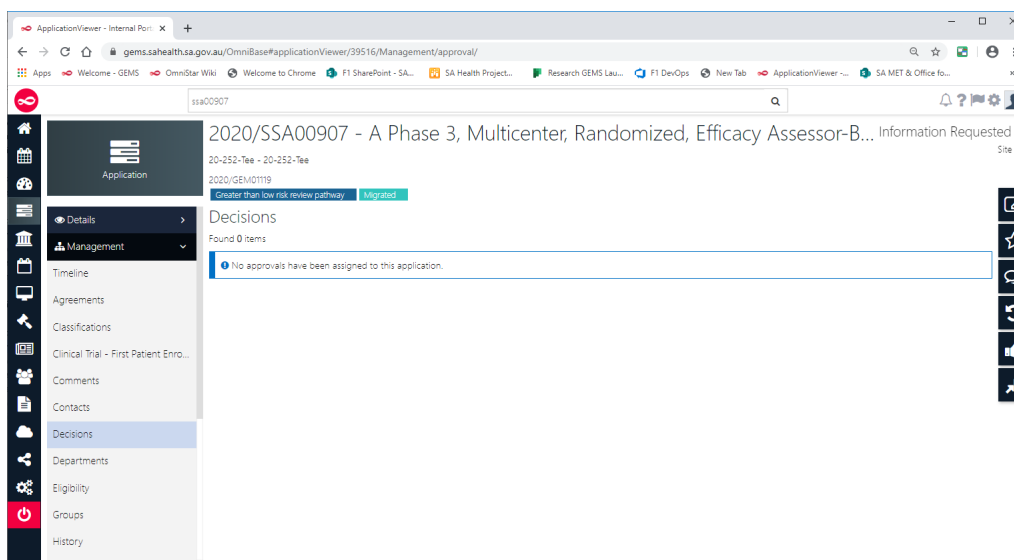


Figure 14: Application decision

The decision can be processed as described in section 4.3 of the training guide.

Note – the decision type 'Decision pending further information' is unable to be used for migrated in-flight applications. If further information is required, it should be sought via email and uploaded to the application in the 'Related Documents' section. In this case, the status of the application should also be updated to 'Information Requested' to stop the clock. Once the information has been provided by the researcher the status can then be updated to 'Information Provided' to start the clock again.

Once the RGO decision has been recorded, a 'CE/Delegate decision' is created. If the CE decision has already been made it can be recorded in Research GEMS by overriding the decision, which ensures the CE is not notified. This can be done by:

1. Click the documents icon next to the 'CE/Delegate decision'
2. Drag the approved briefing into the 'Click of drop your file here' area
3. Select the type 'RGO brief' and click Save
4. Close the documents area
5. Click the edit icon next to the 'CE/Delegate decision'
6. Click on the toggle next to 'Override outcome' changing it to 'Yes'
7. Select the outcome from the drop down list
8. Add detail regarding the decision in the comments section and click Save

If the decision is not retrospective, the CE decision can be processed as per section 4.3.1.2 of the training guide.

CALHN governance application only

An additional step is created for a 'Recommendation by the RM' before the 'CE/Delegate decision'. This can be processed as per section 4.3.1.3 of the training guide, or processed in the same way as described above for retrospective CE decisions.

4.5 Sending an application decision notification

If the PI has not been informed of the application decision, you can send the decision email as per section 4.4 of the training guide whilst noting the following information.

Research GEMS presents users with email templates appropriate to the decision being made. These emails may contain links to applications and may request the researcher to update applications and add or amend supporting documents.

Before sending the emails, the Research Governance Officer should review the email as follows:

- If the email contains links to access application documentation, that all documentation has been uploaded
- Check and update application decision date and expiry date
- Check for and update broken tokens which will appear in curly brackets, as the required data may not be available for the in-flight application

If the PI has already been notified of the application decision, you can skip sending the decision email from GEMS by replacing the PI email address with your own email address in the To: field. Ensure the original decision email or letter has been uploaded to 'Related documents' if this is the case.

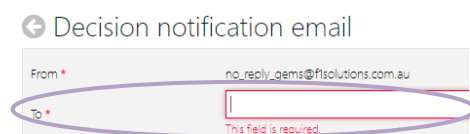


Figure 15: Eligibility check email

4.6 Updating the application and project approval date and expiry date

The application and project approval and expiry date may need to be updated for applications processed in GEMS. After recording the decision, check the 'Summary' page on the application AND project to ensure the approval and expiry date are correct (see Figure 16 and Figure 17).

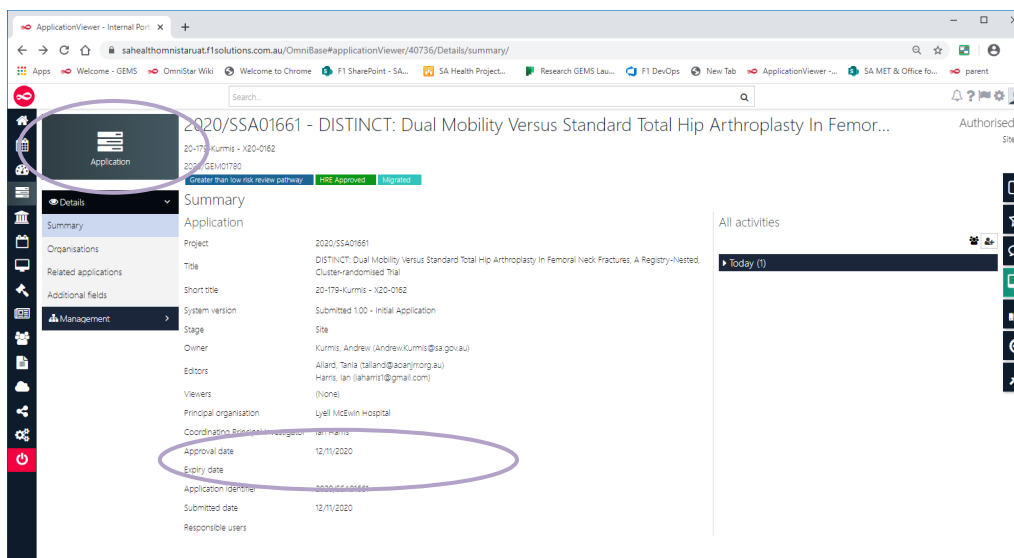


Figure 16: Authorised application summary

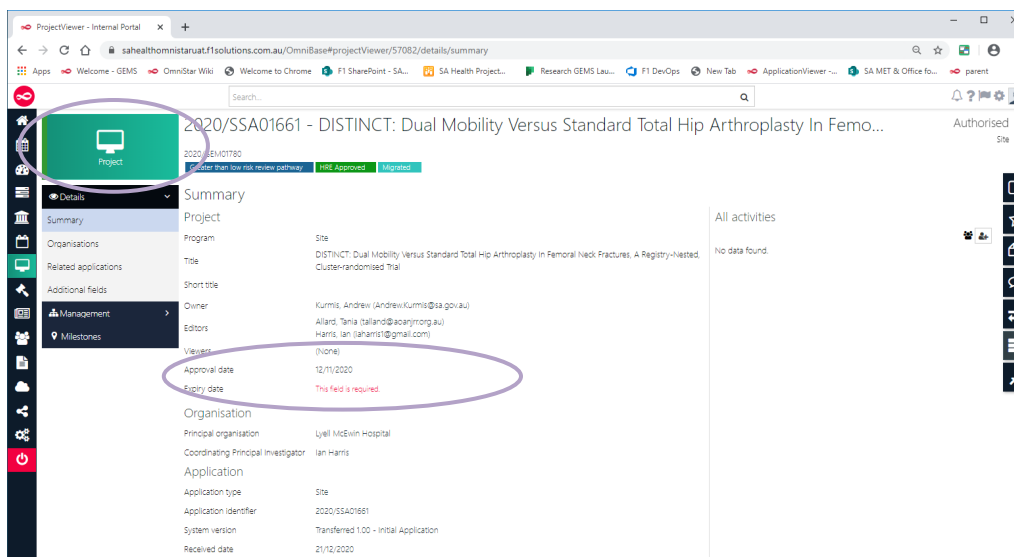


Figure 17: Authorised project summary

If the approval or expiry dates are blank or incorrect, update them on both the application and site project:

1. On the application, click on the 'Edit' icon on the right hand side
2. Edit the approval and expiry date fields and click Save
3. On the project, click on the 'Edit' icon on the right hand side
4. Click on the 'Change project start date' button
5. Set the approval date and click Save
6. If required, edit the expiry date then click the Save icon on the right hand side

4.7 Checking the project

After processing the application decision, the Research Governance Officer should check the project as per section 4.4.1 in the training guide.

If the study requires a 'Certificate of Currency' milestone, check the project to ensure it has been added.

5. Addition of new sites through an 'administrative amendment'

There may be cases where an ethics application was migrated to Research GEMS, however the associated governance application was not received prior to the migration cut-off date. In these circumstances, an 'administrative amendment' will be required in order to create the site application in Research GEMS. It is important to note that this process should only be used if the associated site was listed on the Ethics application and approved by the HREC. If the associated site was not listed on the Ethics application, the standard amendment process should be followed.

To submit an administrative amendment ask the Researcher to submit an ethics amendment form to add a new site. The Research Governance Officer should communicate with the HREC Executive Officer informing them that an 'administrative amendment' will be submitted.

After ensuring that the site was included in the ethics approval, the Executive Officer can proceed with an 'administrative amendment' by process the amendment through a decision as per section 3.2.4 of the training guide, noting in the decision comment that the site was included in the prior ethics approval.

6. Post Approval Monitoring

6.1 Checking the project contacts

Before processing post approval monitoring, the Executive Officer will need to ensure that a CPI has been recorded against the ethics project. Similarly the Research Governance Officer will need to ensure that a CPI and PI has been recorded against the site project.

If a CPI or PI is not recorded against the project the post approval monitoring notifications will not be sent to the required recipients. To check whether a CPI and PI exists, open the application in the Application Viewer, go to the project, then to the Summary screen and look for a name against the 'Coordinating Principal Investigator' for an ethics project, and the 'Owner' (PI) and 'Coordinating Principal Investigator' for a site project (see Figure 18).

Please contact the Research GEMS team if the application you are processing is missing a 'Owner' (PI) and/or 'Coordinating Principal Investigator'.

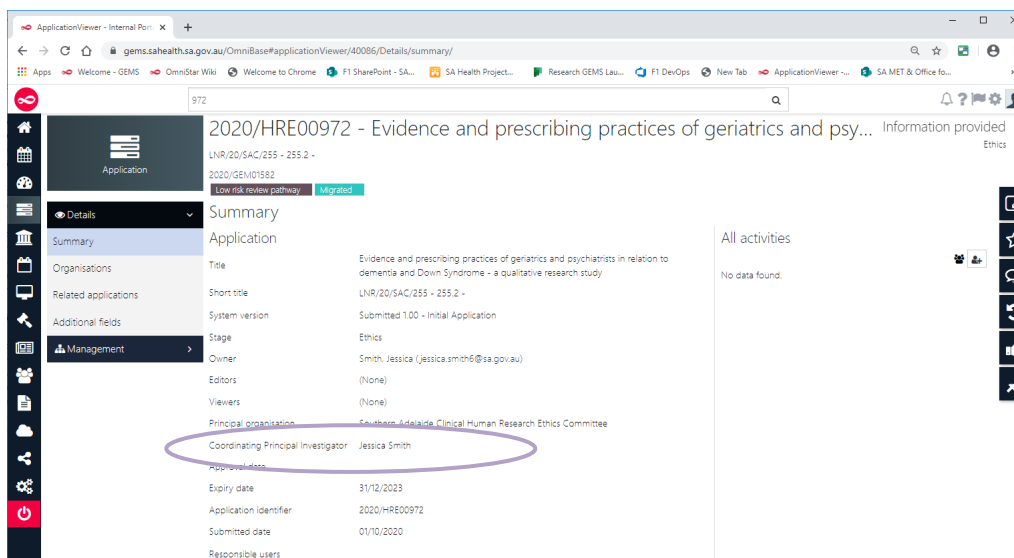


Figure 18: Application Contacts

6.2 Uploading application documentation

The migration of applications did not bring across supporting documents. Before processing any post approval monitoring for migrated applications, the application documents need to be manually uploaded. The upload is performed on the Application Viewer Related Documents screen. To access the screen, display the application in the Application Viewer and select Related Documents in the left menu.

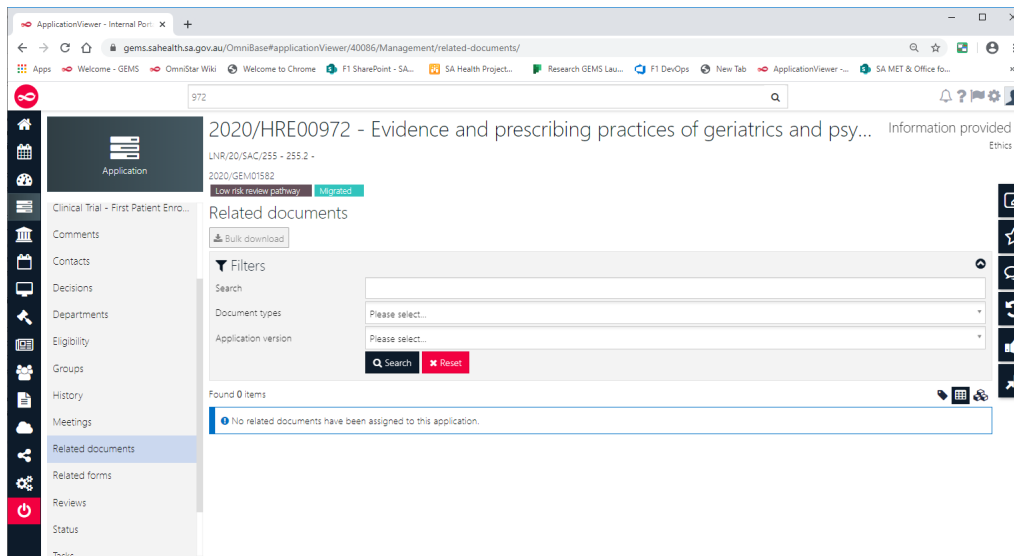


Figure 19: Application related documents

To add documents to an application:

7. Select the Edit icon in the top right. Then click on the '+ Add document' button
8. Either drag the files into the 'Click or drop your files here' area or click to the select files
9. After files have been uploaded, the document type needs to be selected

10. Select the appropriate document type from the drop down list for each file then click the Save button
11. Ensure the documents are shared with the related sites (in related projects/applications) and the research project team (in Research GEMS) if appropriate. Note that some files (such as briefings) should **not** be shared. Ensure the files are shared as necessary
Check whether the file is shared by hovering over the first two icons next to the file.



Figure 20: File sharing icons

12. If the sharing is incorrect, click on the icon to change the setting

6.3 Processing post-approval monitoring

Post approval monitoring that has been submitted in GEMS for a migrated application should be processed as per the training guide.

6.4 Processing progress reports

Progress reports for migrated applications should be processed as per section 3.1 of the training guide.

One annual progress report was created for a migrated study. If the HREC approval is for longer than one year, additional milestones will need to be created.

After processing the progress report for a migrated study, check the project to ensure all required progress reports exist, and create any additional milestones as per section 2.5.6 of the training guide.

6.5 Sending an application decision notification

Research GEMS presents users with email templates appropriate to the decision being made. These emails may contain links to applications and may request the researcher update applications and add or amend supporting documents.

Before sending the emails, the Executive Officer/Research Governance Officer should review the email as follows:

- If the email contains links to access application documentation, that all documentation has been uploaded
- Check for and update broken tokens which will appear in curly brackets, as the required data may not be available for the in-flight application