Australian Government

National Health and Medical Research Council

Human Research Ethics Application (HREA)
How-to Guide

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Version 3.1

Contents

Introduction

This guide contains step-by-step instructions on how to carry out all the key stages in using the HREA to prepare, finalise and submit an ethics application to a Human Research Ethics Committee (HREC), from creating your account to revising and re-submitting a previously submitted application.

Before using the HREA, it is recommended that you review the additional HREA guidance available at https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-applications-hrea/human-research-ethics-applications-hrea-resources

If you have any questions or feedback, please contact HREA Help at help@hrea.gov.au or **1800 500 983** (within Australia) or **+61 2 6217 9451** (international callers) between Monday to Friday during 9:00AM to 5:00PM AEST/AEDT, excluding public holidays and ACT public holidays.
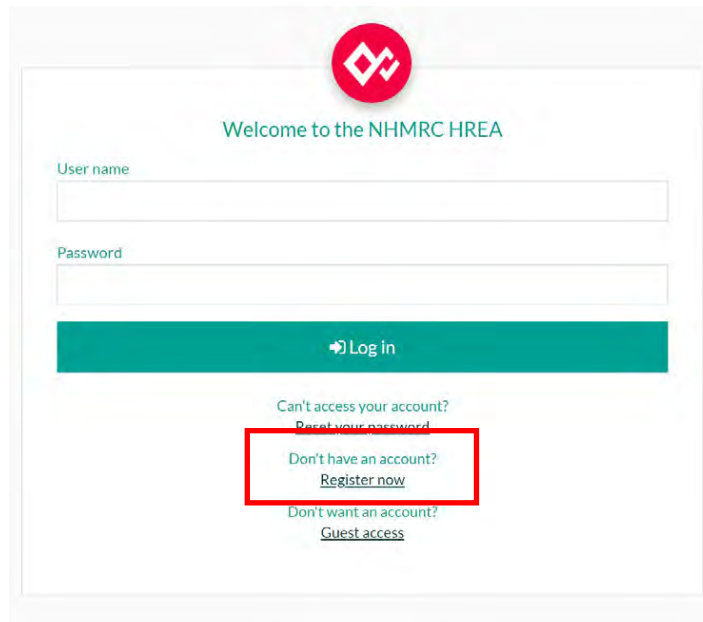
How-to Guide
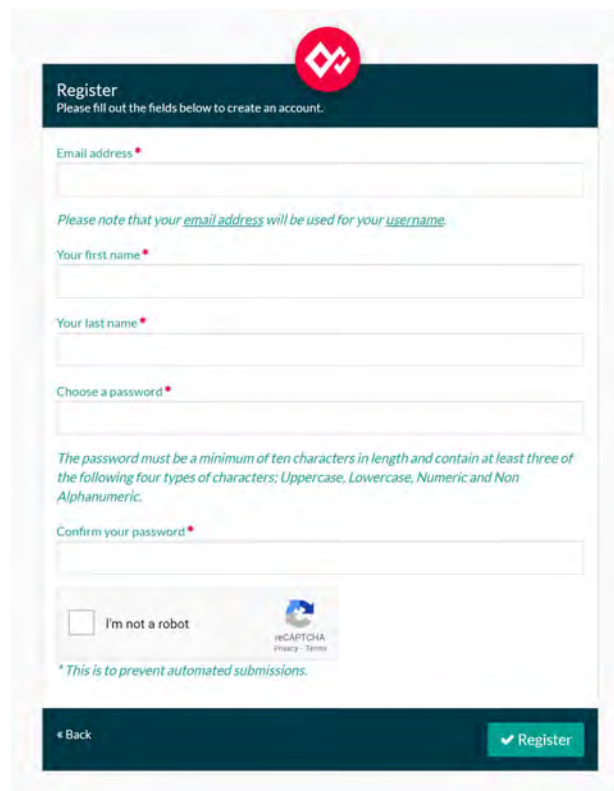
1 Creating and managing your HREA account

1.1 How to create a new account

Navigate to https://www.hrea.gov.au with a web browser.

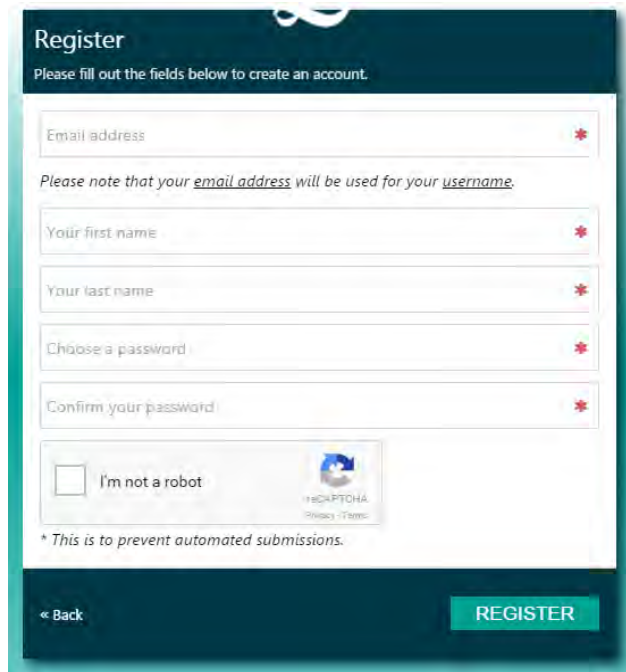1. Select 'Register now' from the sign in page.

2. Complete all the fields on this page. Note that the password must consist of at least 10 characters, comprising at least three of the four types of characters: lower case letter, upper case letter, number and symbol **(e.g. @!#).** The password box will turn green once the complexity requirements are met.

3. Help on using the **reCAPTCHA** (https://www.google.com/recaptcha/api2/demo; a Google resource to prevent malicious software) is available here: https://support.google.com/recaptcha/?hl=en.

4. Select the 'Register' button once you have completed all fields.

5. You will receive an email confirming your registration with a web link included. Click on this web link to activate your account. If you do not receive an email within 5 minutes, please check your spam/junk email folder. If the activation email is not there, please reset your password following the reset password instructions below.

1.2 How to sign in to your HREA account

Navigate to https://www.hrea.gov.au with a web browser.

1. Enter your username (the email address used for registration) and password on the sign in page, then select 'Log in'.

2. Select 'Agree' to accept the licence agreement and enter the HREA.

1.3 How to reset a forgotten password

1. Select 'Reset your password' from the sign in page.

2. Enter your username (the email address used for registration), complete the reCAPTCHA test and select 'Reset password'.

3. An email will be sent to the specified email address containing a link to reset the password.
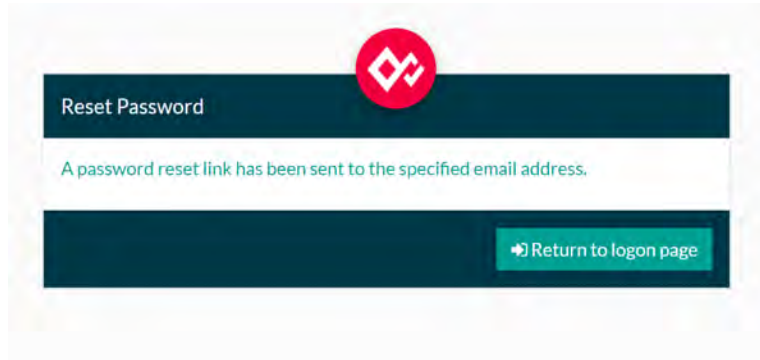
4. Open the email and click on the reset password link (or paste the URL into your web browser).

5. Type in a new password. Note that the password must consist of at least 10 characters, comprising at least three of the four types of characters: lower case letter, upper case letter, number and symbol. The password box will turn green once the complexity requirements are met.

6. Select 'Set password'.
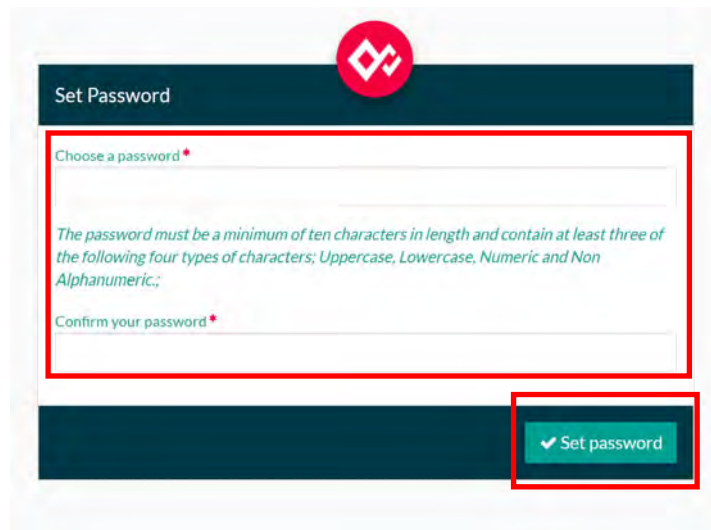
7. If you have successfully reset your password you will see the notification below:

1.4 How to manage your profile

1. Sign in to your HREA account.

2. Select the 'Profile' button on the HREA Portal page.

3. Select the profile component to modify from the left hand menu.

4. Amend details and select 'Save'.

1.5 How to change your username

1. Sign in to your HREA account.

2. Select the 'Profile' button on HREA Portal page.
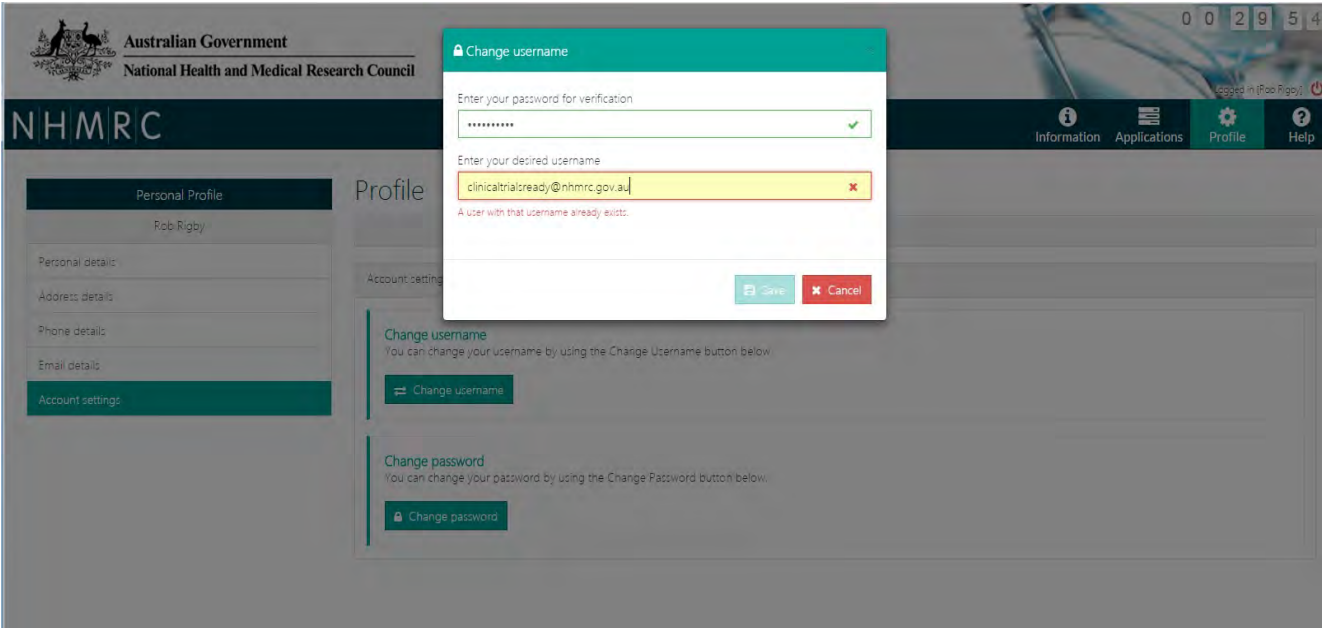

3. Select 'Account settings'.
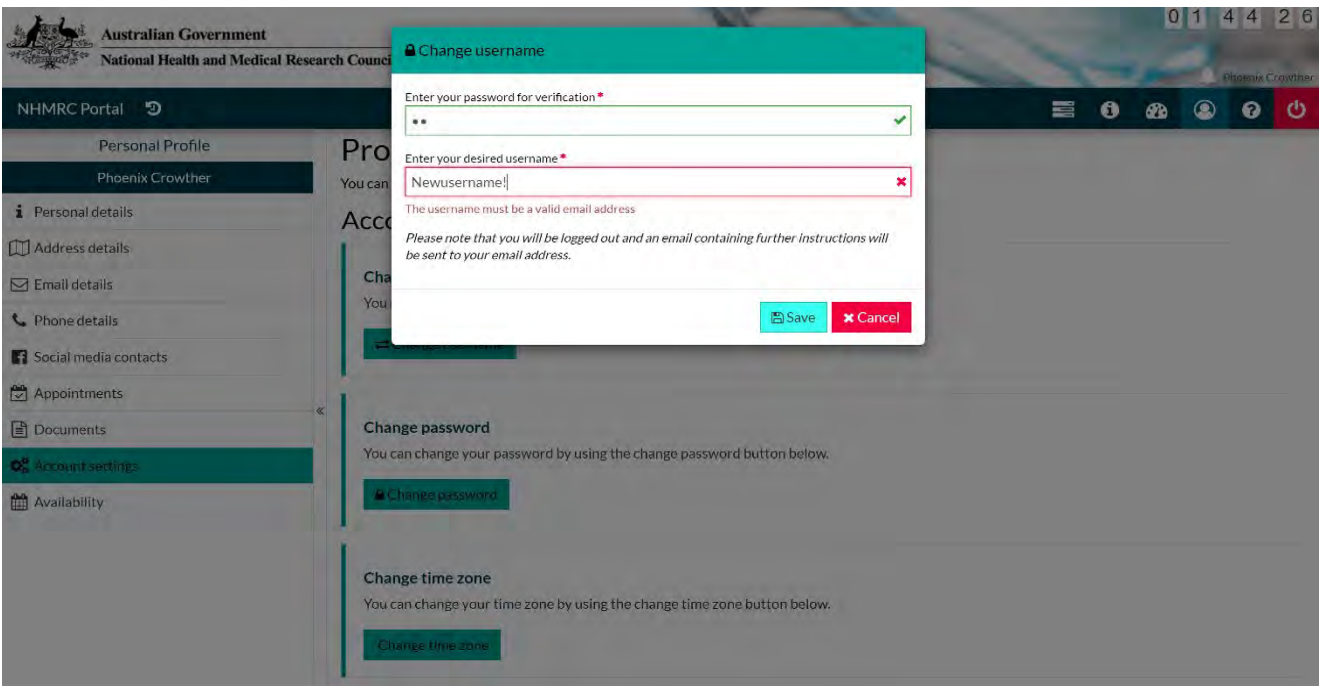
4. Select 'Change username'.

5. Enter your password and the new username, then select 'Save'. Note that the username must be an active email address.
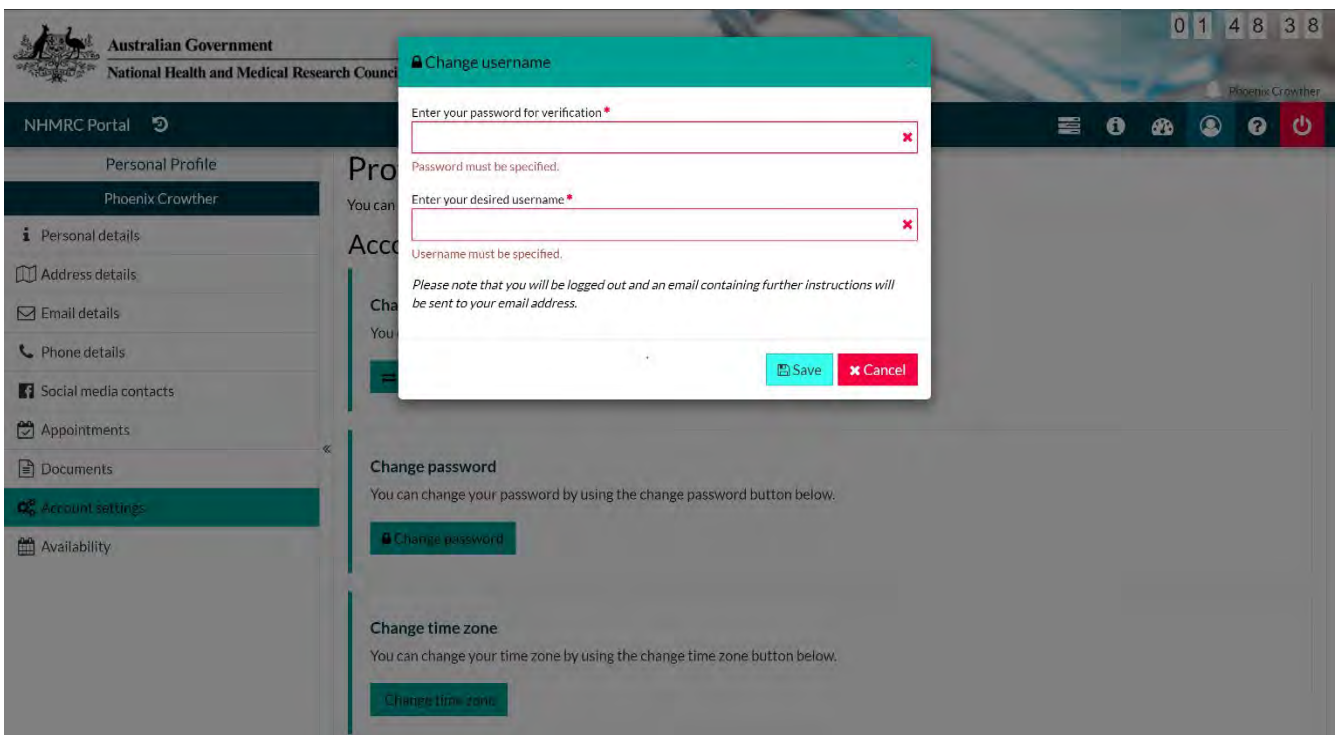
You will be informed if the new email address has an existing account associated with it.
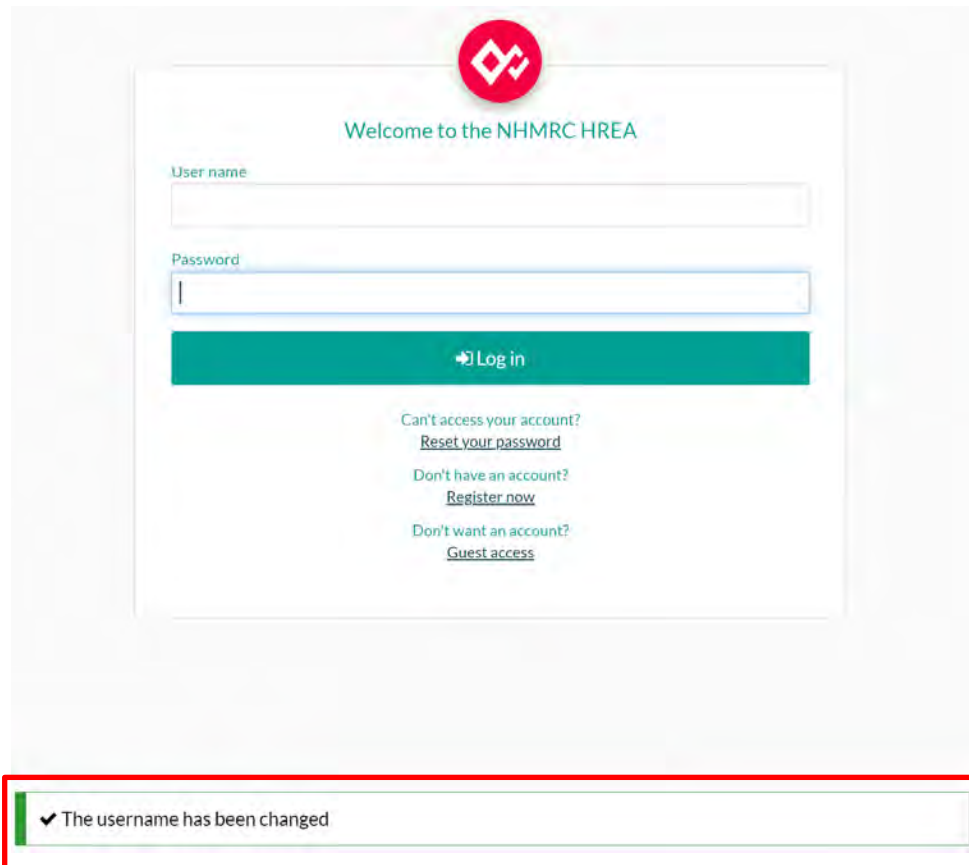

You will also be informed if the new username is not in the correct email address format.
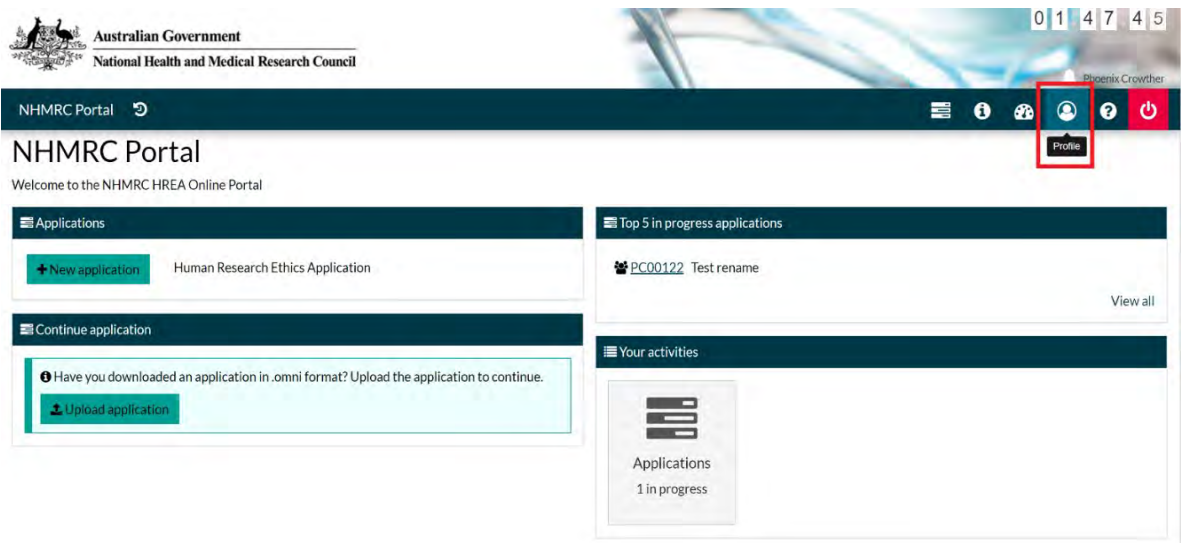

6. You will be logged out from the HREA Portal and an email will be sent to the original email address with a web link for you to verify the change to the username. You must access this email and click on the link to confirm the change of username.

7. Clicking on the link in the email will display the HREA home page with confirmation at the bottom of screen that the username has been changed. Enter the new username and password to confirm the change has occurred.
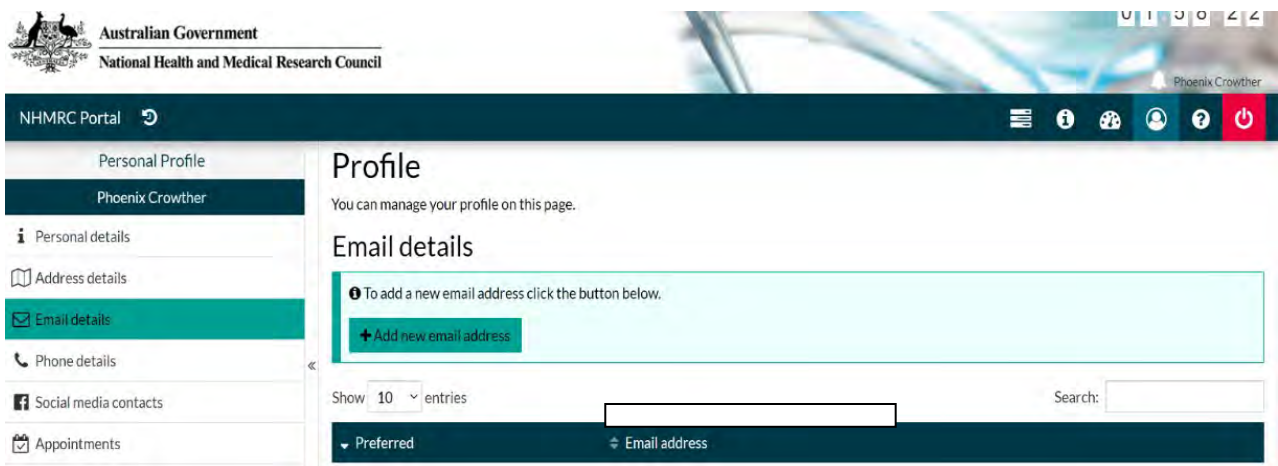

✔ The username has been changed

8. To make sure that emails are now sent to your new username, select the 'Profile' button on the HREA Portal page.

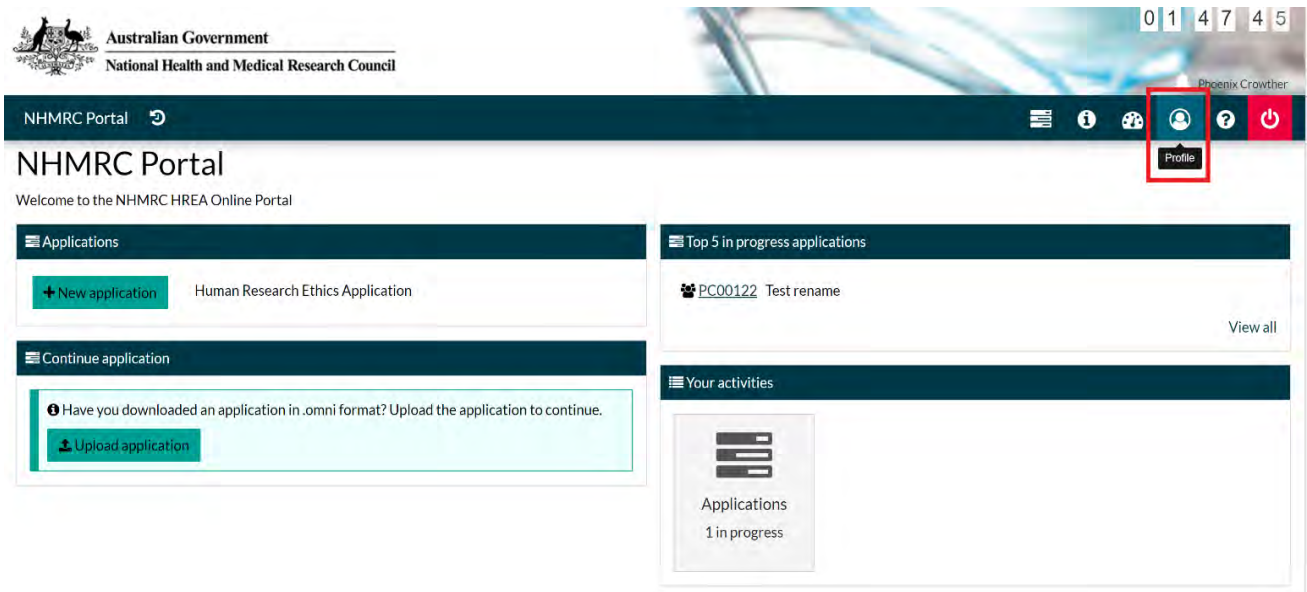9. Select 'Email details'.

10. Select 'Add new email address'.

11. Enter the new email address (your new username), tick 'Preferred' and select 'Save'.

1.6 How to change your password

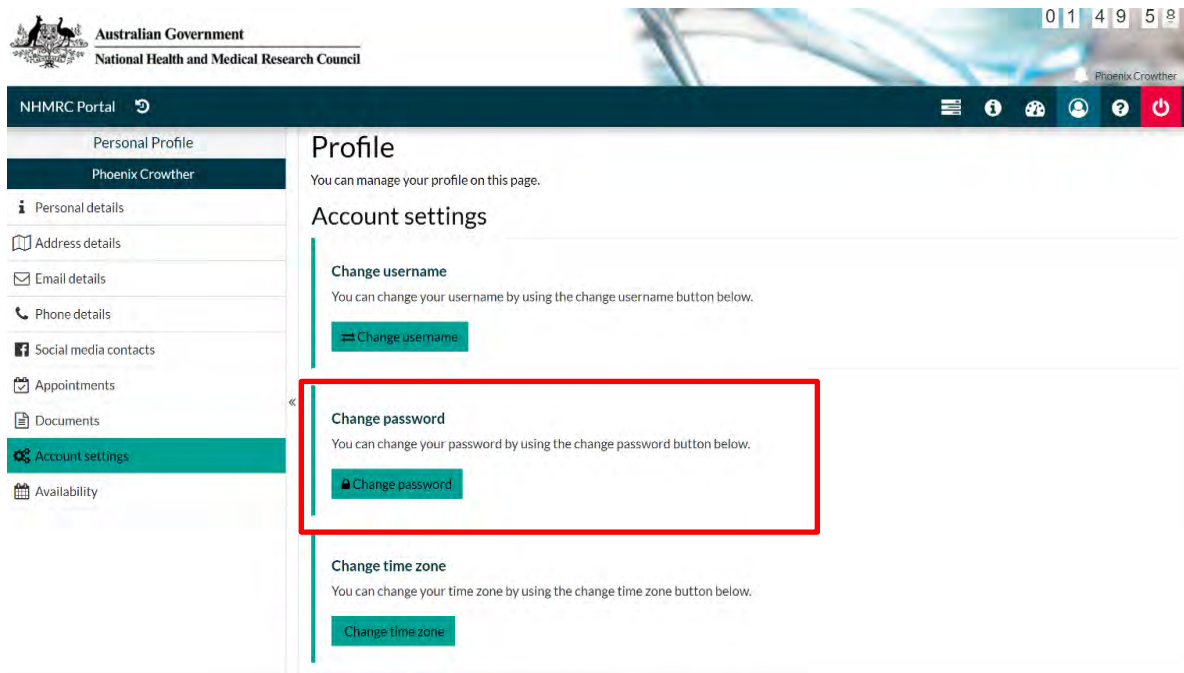1. Sign in to your HREA account.

2. Select the 'Profile' button on HREA Portal page.

3. Select 'Account settings'.
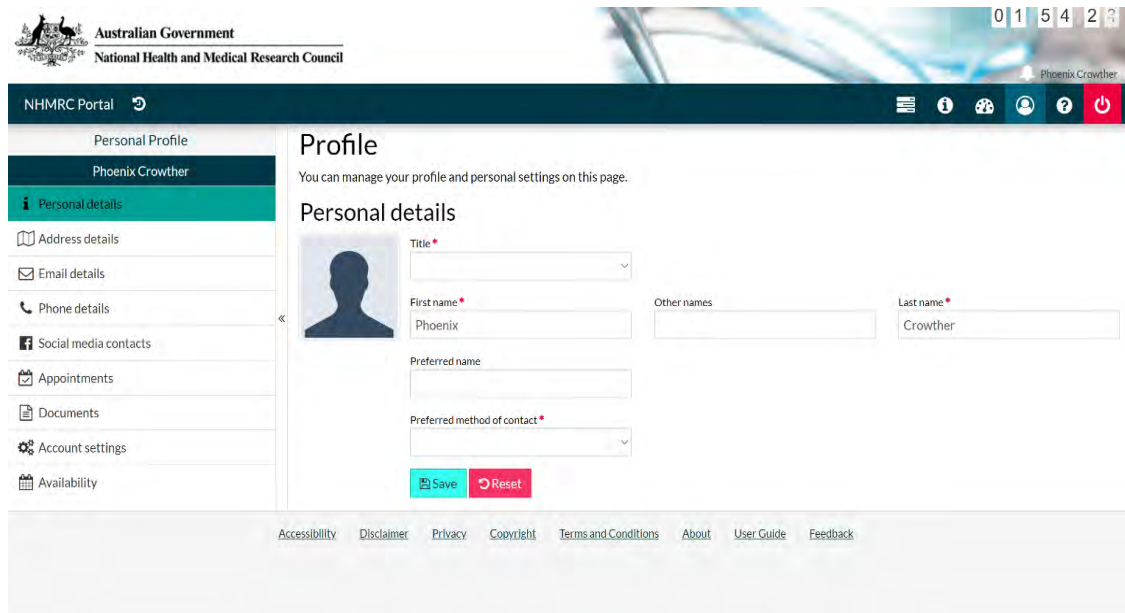
4. Select 'Change password'.

5. Enter the current password and the new password and select 'save'. Note that the password must consist of at least 10 characters, comprising at least three of the four types of characters: lower case letter, upper case letter, number and symbol. The password box will turn green once the complexity requirements are met.
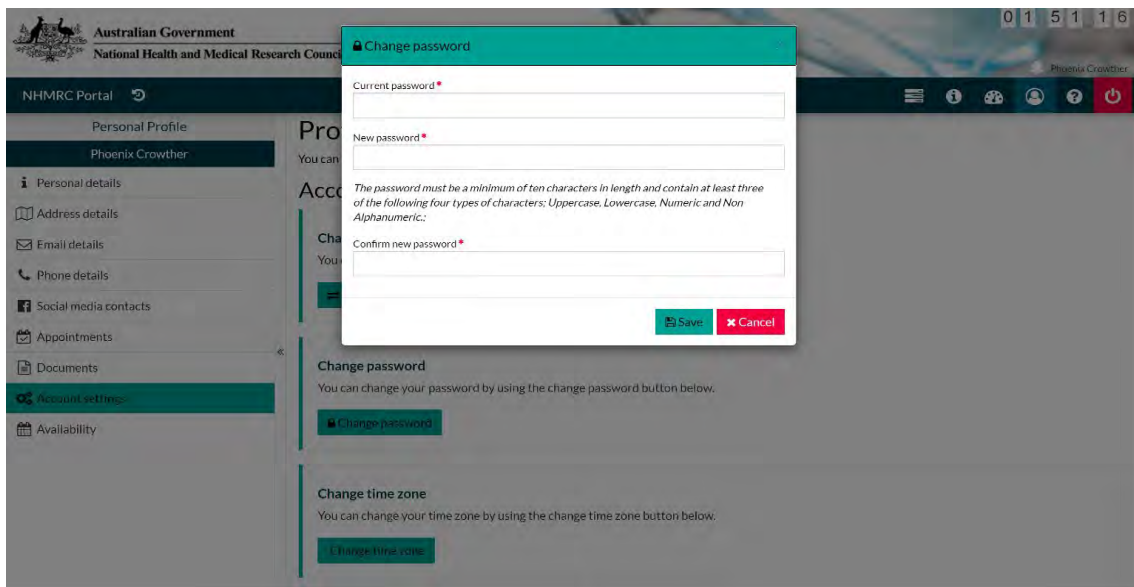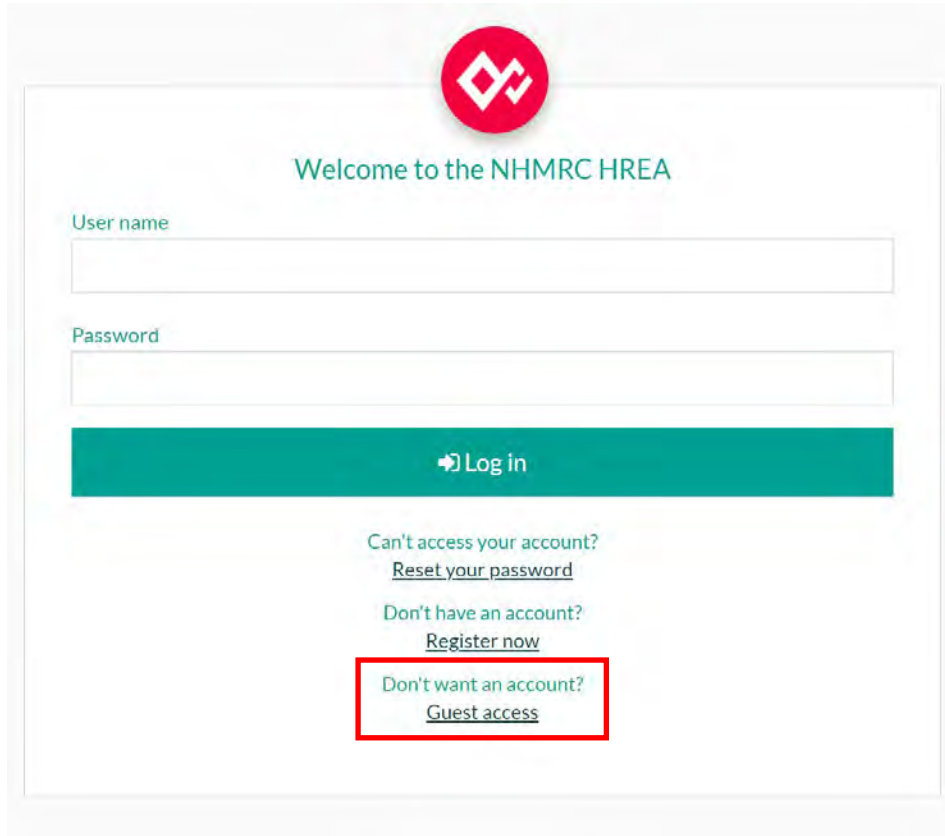

6. The change to the password will be confirmed on-screen.

1.7 How to access the HREA as a Guest

Navigate to https://www.hrea.gov.au with a web browser. Note that an application created using guest access cannot be saved in HREA; you will need to download the .omni file in order to save and re-upload your application at a later time. See **3.1 How to finalise and submit your application** for information on how to save your .omni file.

1. Select 'Guest Access'.
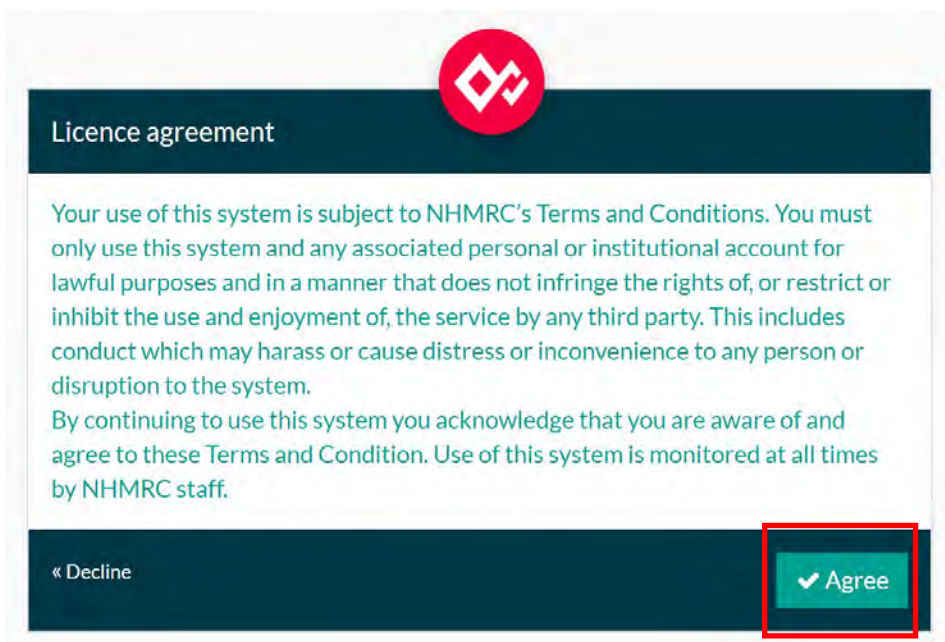
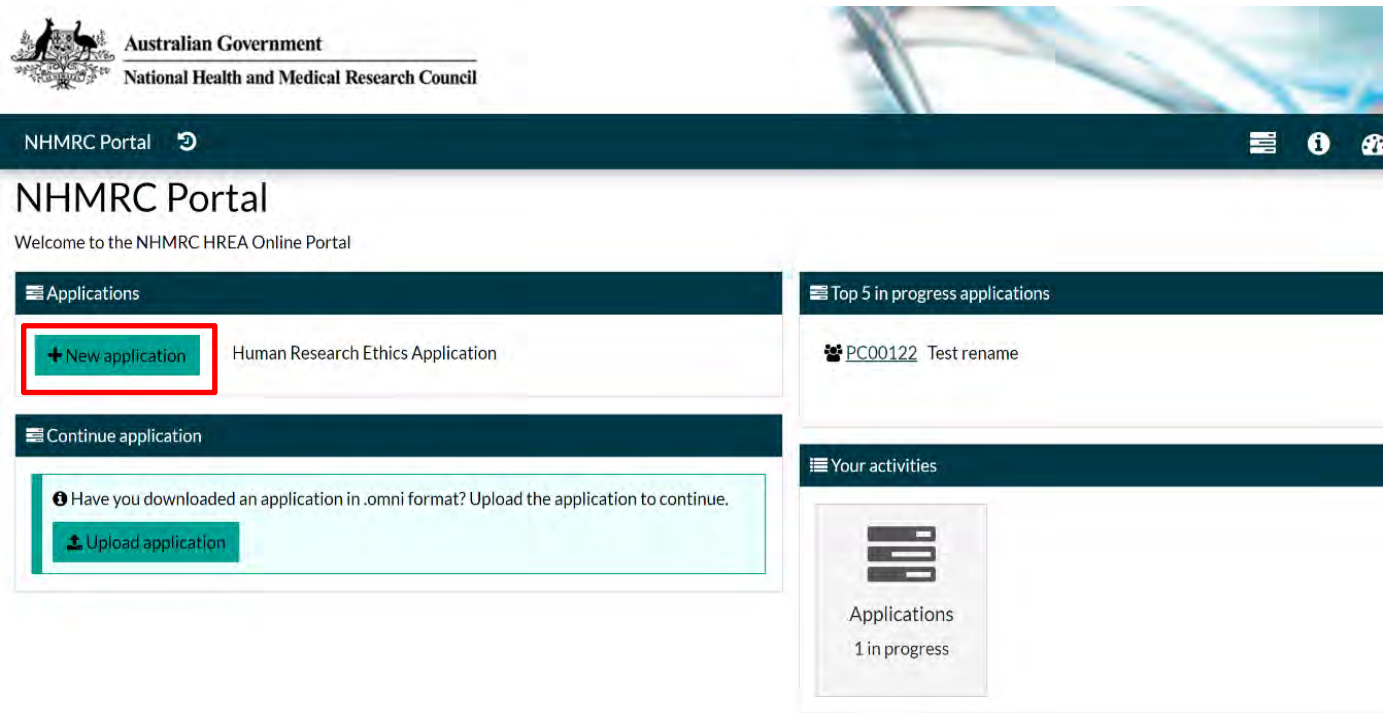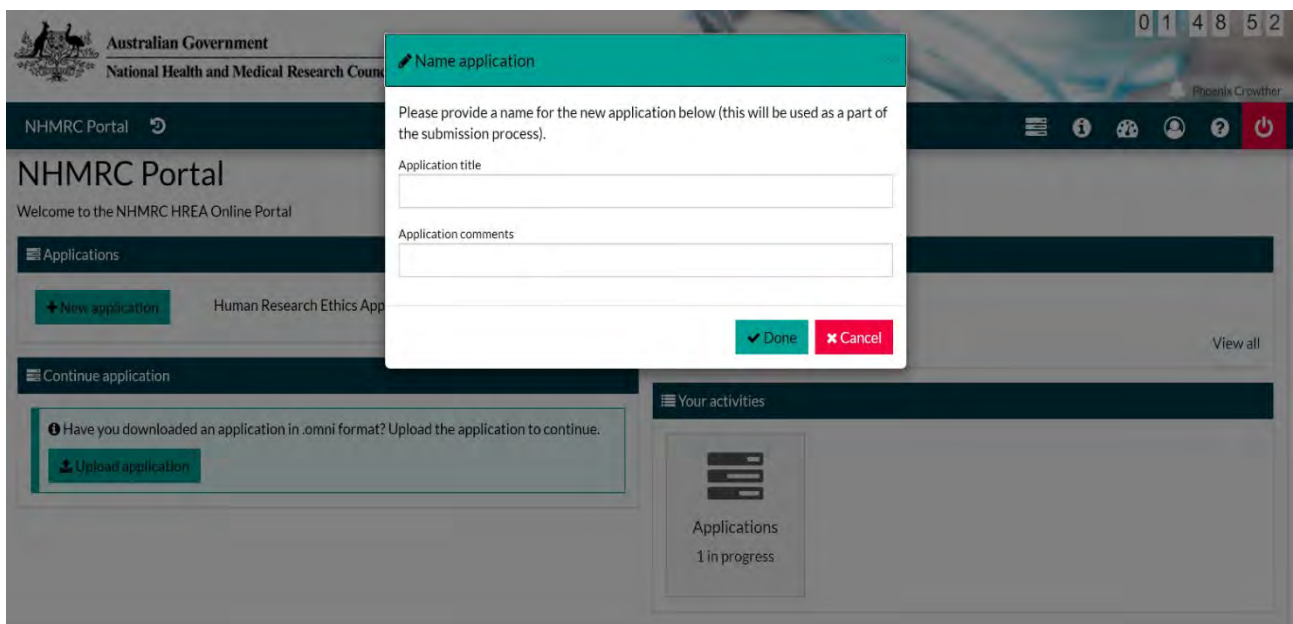2. Select 'Agree' to accept the licence agreement and enter the HREA.

2 Creating your ethics application

2.1 How to start a new application

1. Sign in to your HREA account or as a guest.

2. Select the 'New application' button.

3. Enter an Application title, any comments you want to include and select 'Done'.

4. This will take you to the first page of the HREA. You must select 'Acknowledge and Continue' at the bottom of the Introduction page to access the questions. From here, you can answer HREA questions and complete your application.

2.2 How to share your application

The HREA allows you to share your HREA online while it is being prepared. This feature can be used to invite anyone to review and amend your application. If you invite someone without a HREA account, they will be prompted to create an account.

1. Navigate to the 'Applications' page

2. Identify the application you wish to share and select the 'Options' button (three dots on the left side of the Identifier).
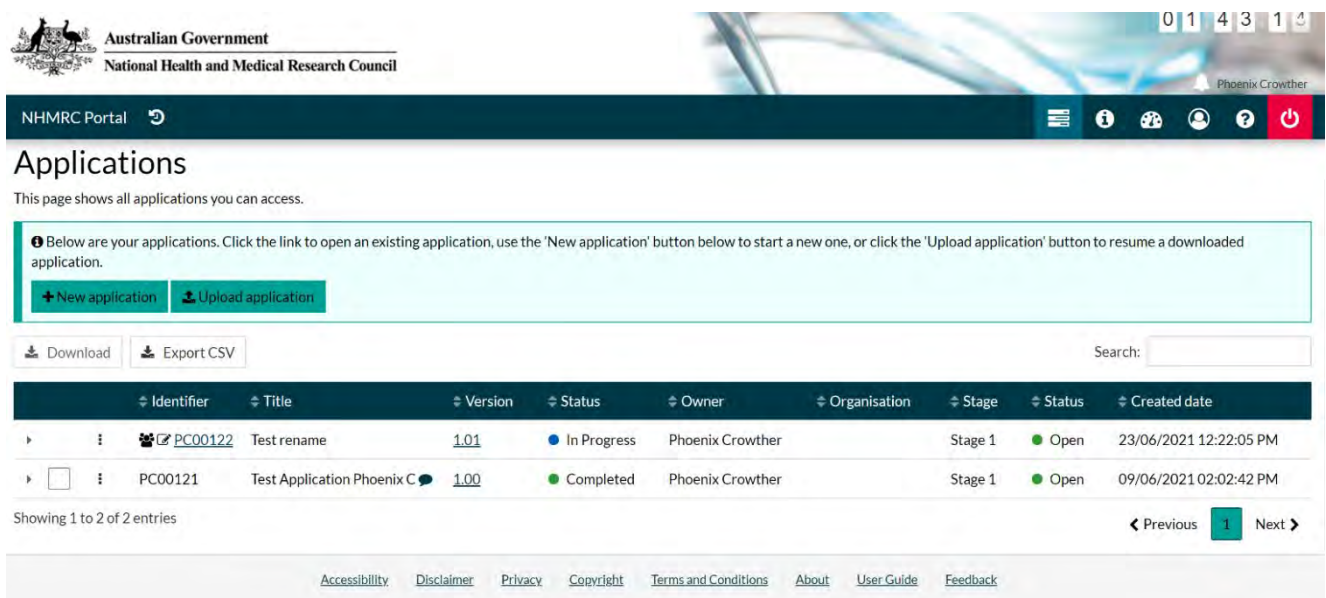
3. Select the 'Invite user to register or share application' button.

4. Enter the username (i.e. the email address) of the person with whom you wish to share the application. They will be added to the list of assigned users. Select from either the 'View' or 'Edit' access option. 'View' will allow the user to open the application but not make any edits to it. 'Edit' will allow the user to open and edit the application.
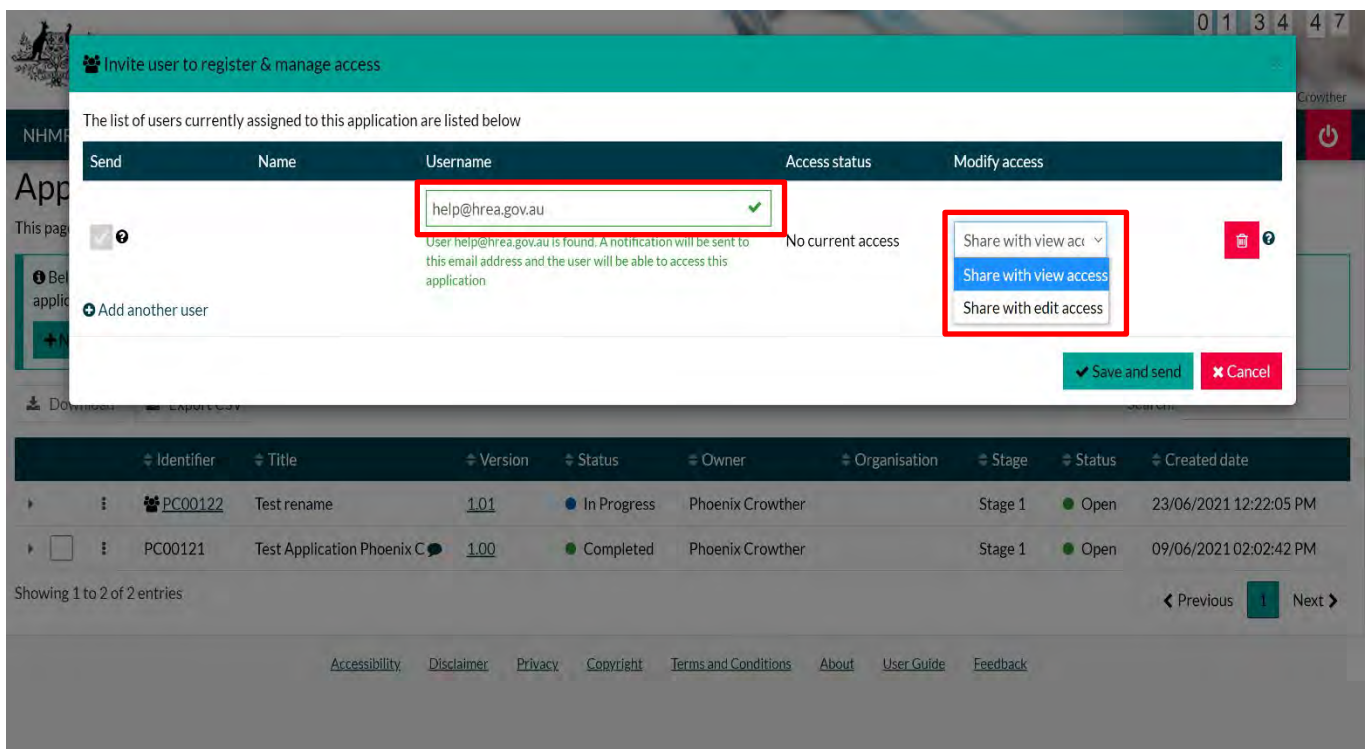
5. Select the 'Save and send' button.
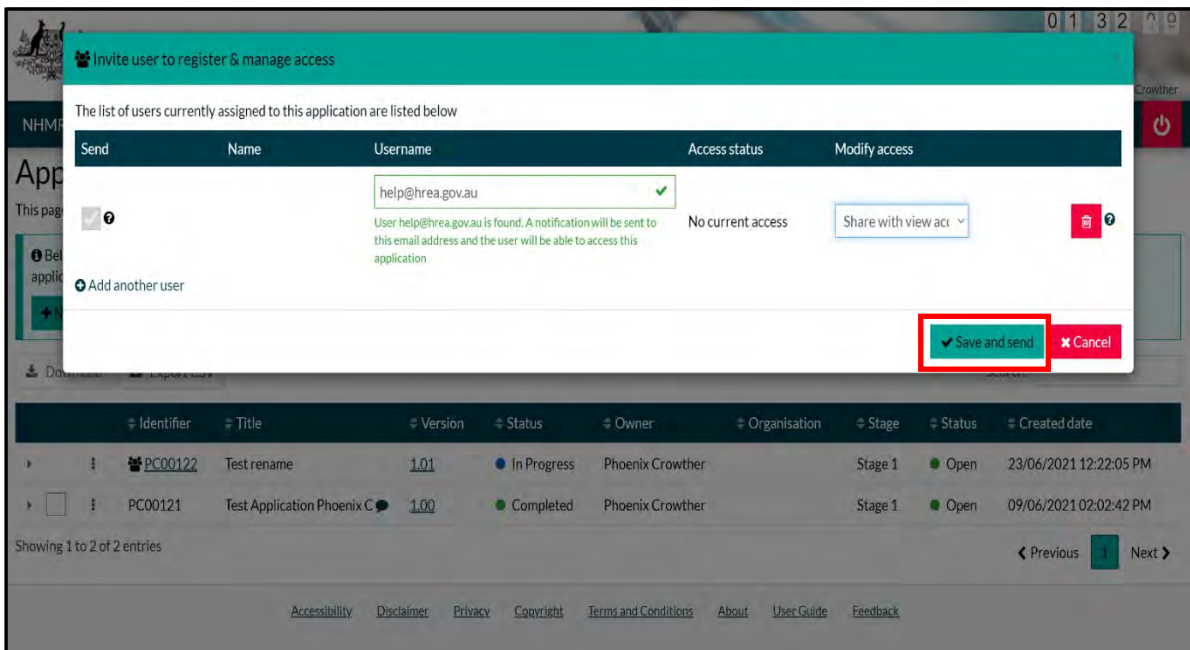
6. The person with whom you have shared the application will receive an email. If the person does not have a HREA account, they will be prompted to create one.
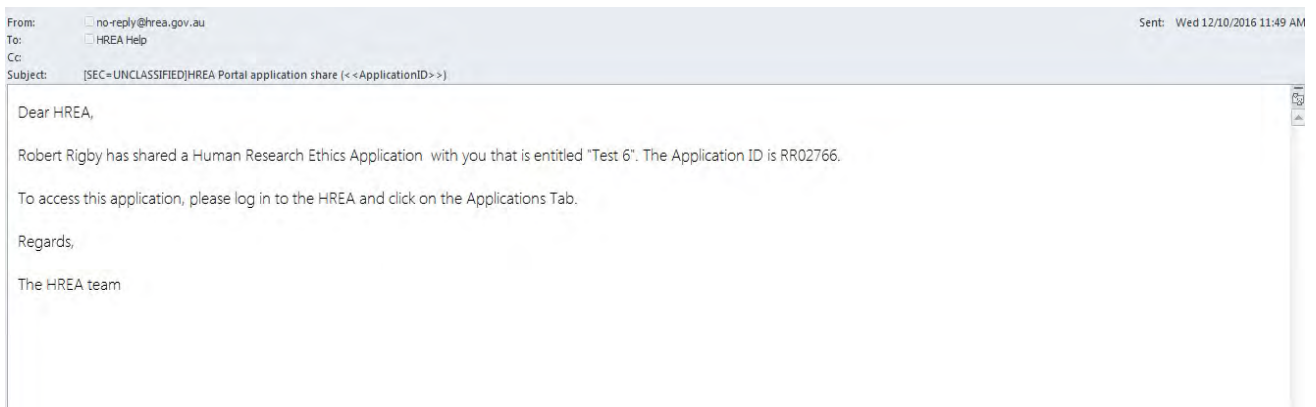
7. The 'Share' icon (on the left side of the Identifier) indicates that an application is being shared. Note that only one person can edit a shared application at a time.

8. To 'unshare' an application, identify the application you wish to 'unshare' and select the 'Options' button on the left side of the Identifier. Note that only the application owner can 'unshare' an application.

9. Select the 'Invite user to register or share application' button.

10. Identify the user/s you wish to remove, select the tick box on the left side of their name, and then select the 'Delete' button on the right side of the access menu.
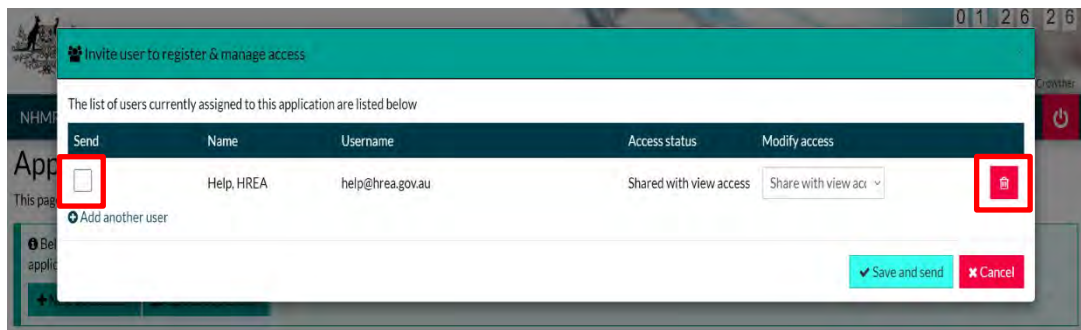
11. Deleted users will no longer appear in the 'Assigned users' list. Select 'Save and send' to complete and return to the 'Applications' list screen.
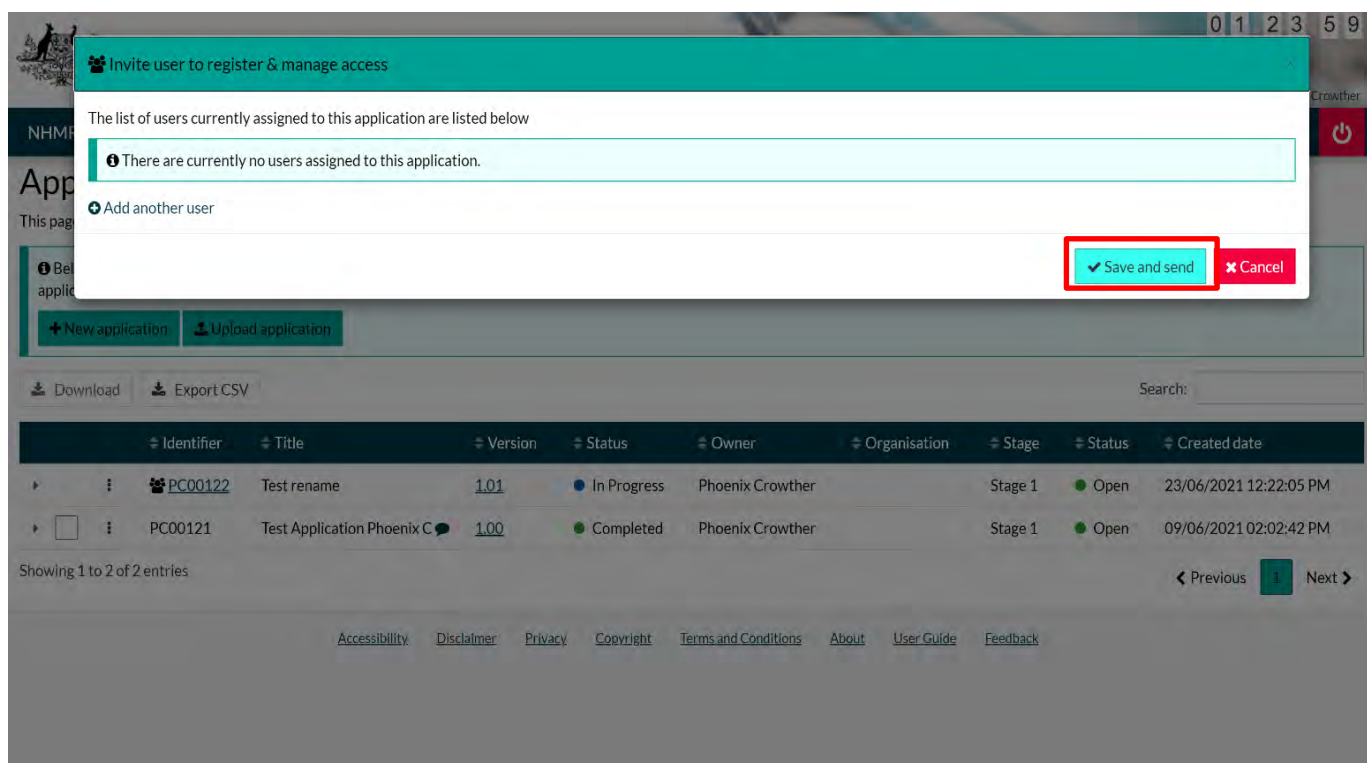
12. Note: If you share an application with another user and provide them with 'edit' access, they will be able to complete the application on your behalf.

13. Note: When an application is completed and generated, it will no longer be shared with other users and will automatically disappear from the list of applications visible to those users. Only the original owner of the application will be able to access it.

2.3 How to attach the Project Description/Protocol

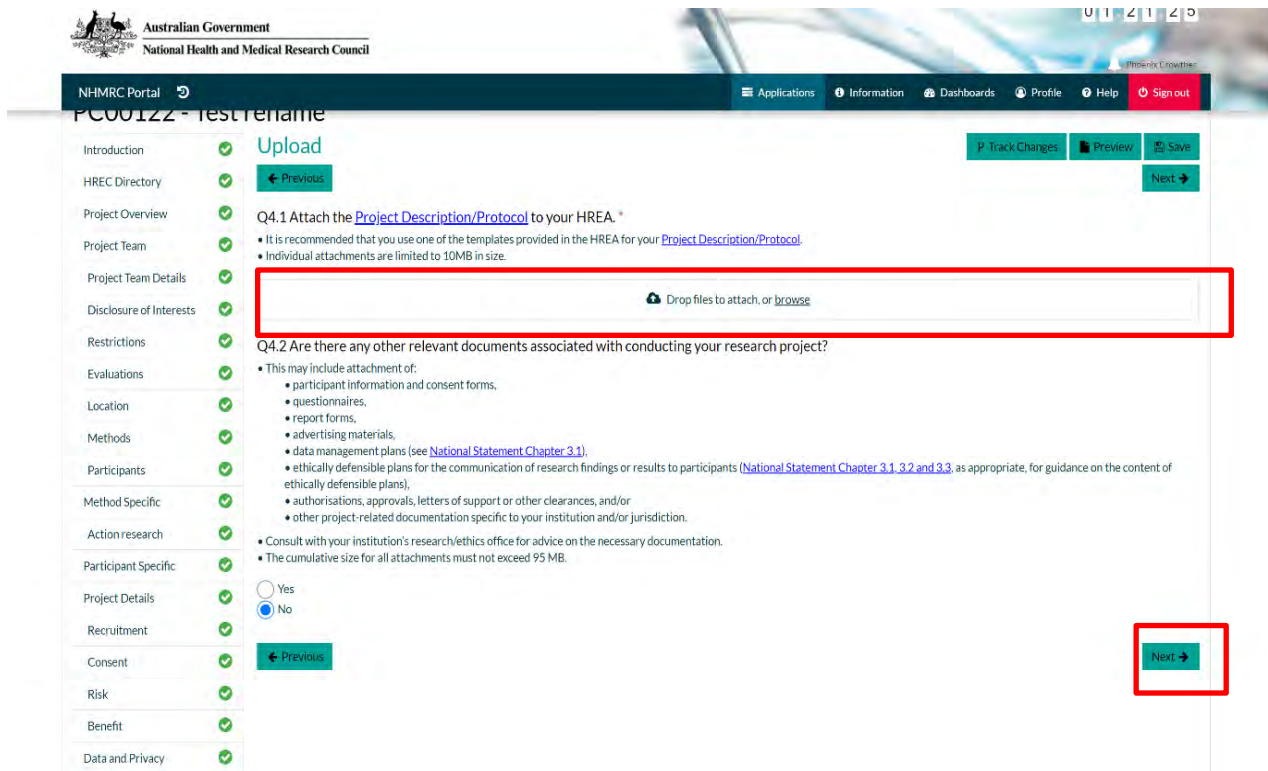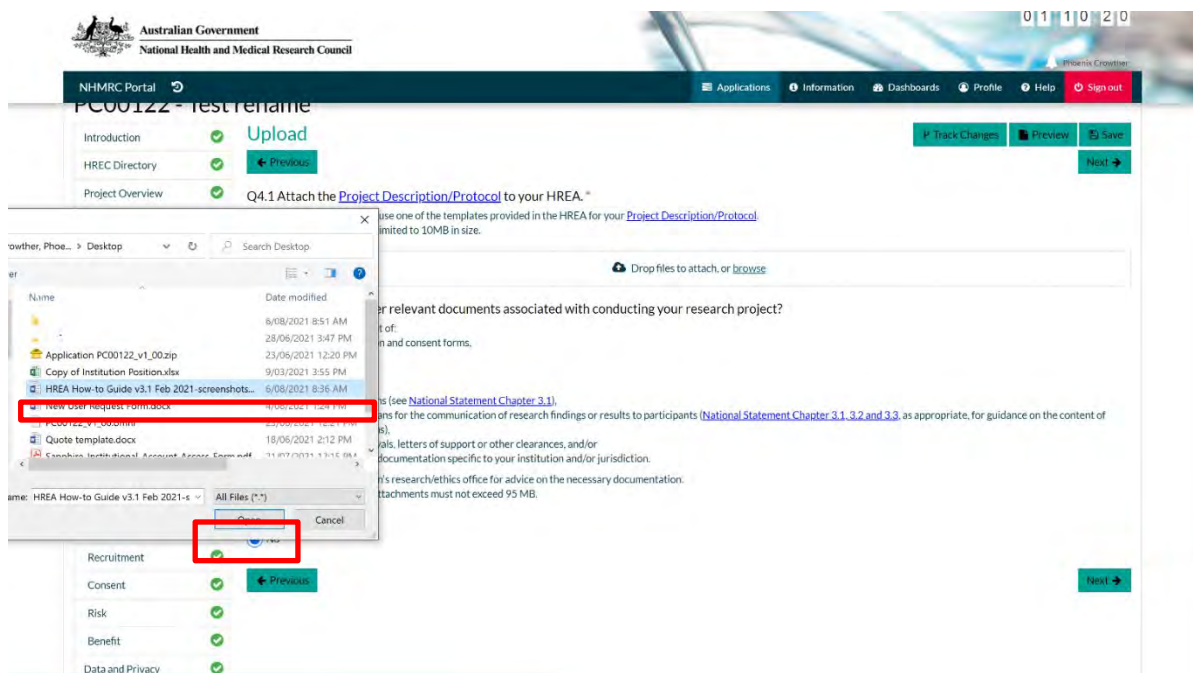Attachment of a Project Description/Protocol to the HREA is mandatory and it is attached separately to any other relevant (optional) documents.
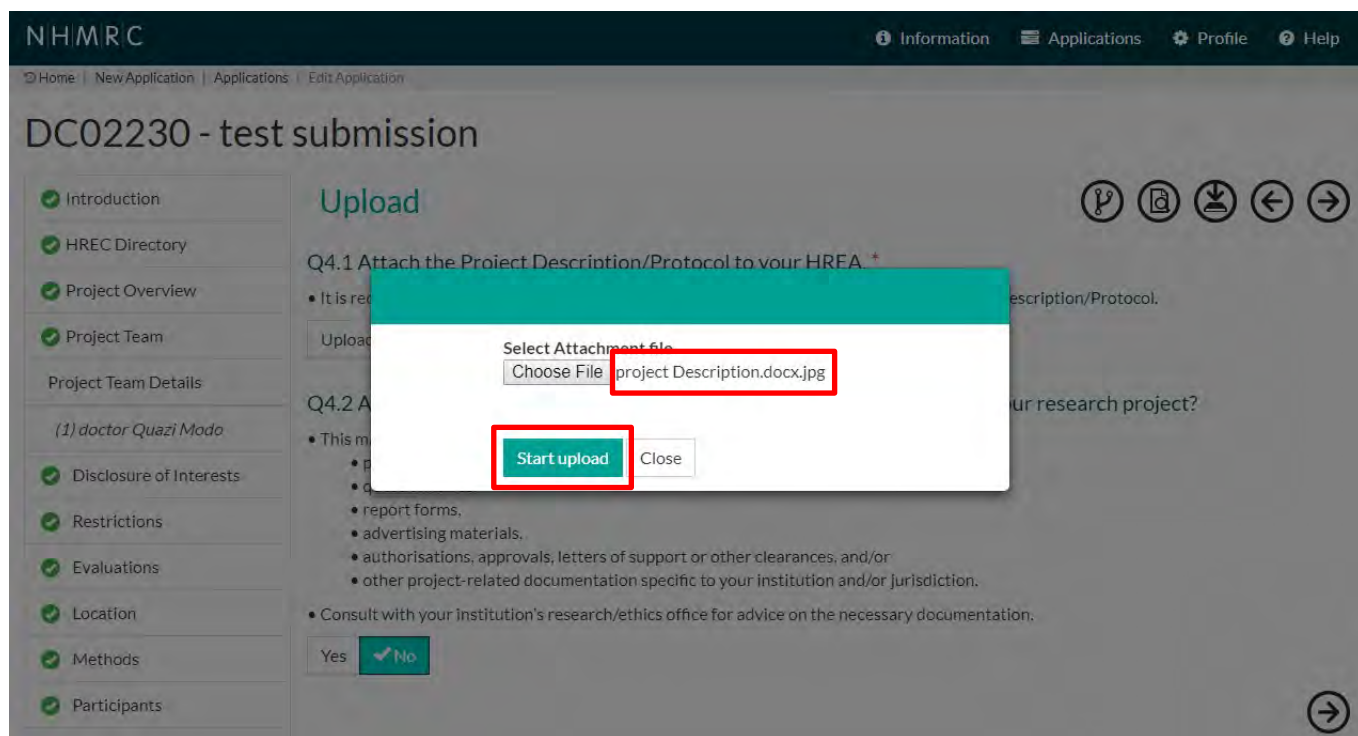
1. Navigate to Q4.1 on the 'Upload' page. Select 'Browse' and the HREA will open the file explorer on your computer.

2. Select the file for attachment and select 'Open'.

3. Ensure the correct filename is displayed and select 'Start upload'.

4. Confirm the correct document has been uploaded. Selecting 'Open' will download and open the attached document. The attached document is a copy of the original document. The original document will remain on your computer.

5. To remove the attached Project Description/Protocol, select the X button on the left side of the file name.

6. **Note:** Please avoid uploading large files (e.g. uncompressed photos) to the HREA. Your application may not open if you have attached files with a cumulative size of 100MB or more.

2.4 How to attach other relevant documentation

Attaching other documents is not mandatory, but other documents may be needed for a particular project. The process for attaching other relevant documents is slightly different to the process for attaching the mandatory Project Description/Protocol.

1. Navigate to Q4.2 on the 'Upload' page.

2. Select 'Yes' at Q4.2 to show the 'Upload attachment' and 'Description of attachment' fields.
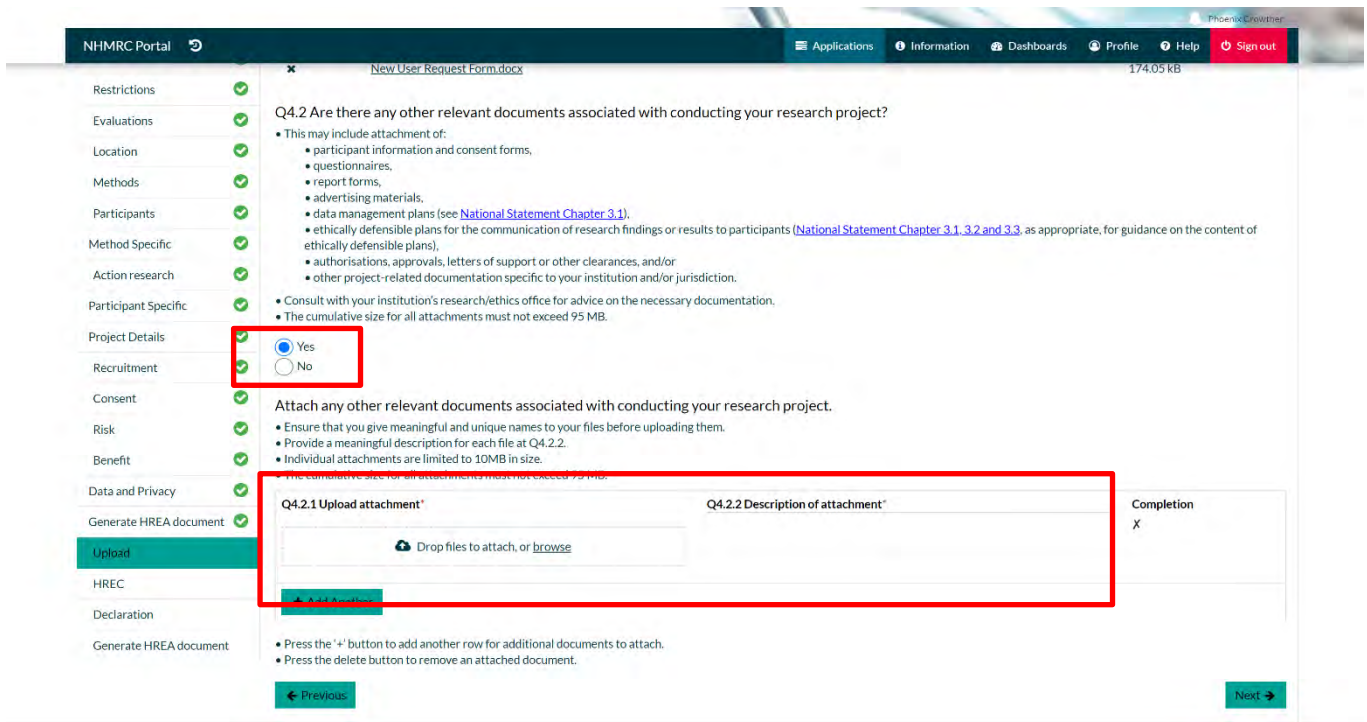
3. To add more attachments, select the 'Add Another' button. In this example, three rows have been added in order to add three separate attachments.
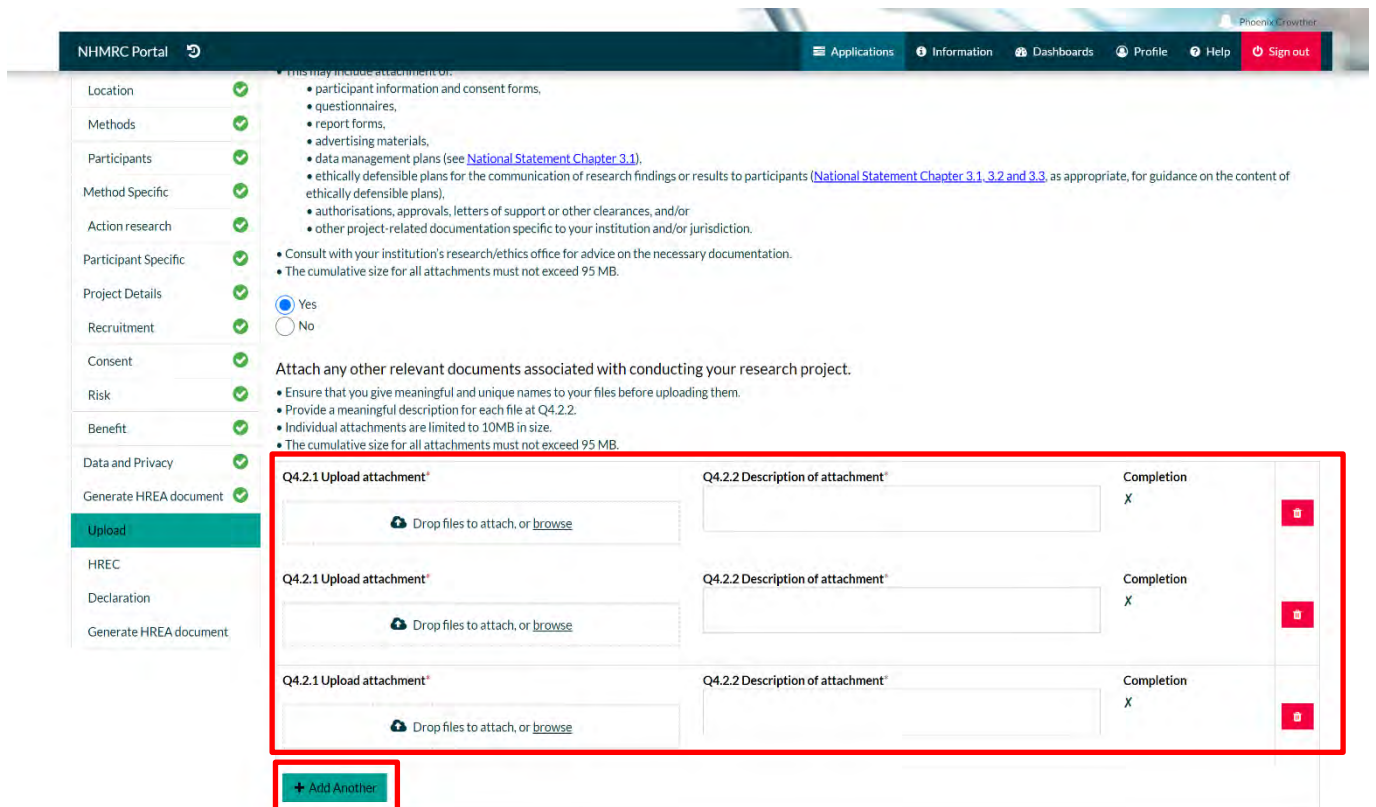
4. To add an attachment, select 'Browse' and the HREA will open the file explorer on your computer.
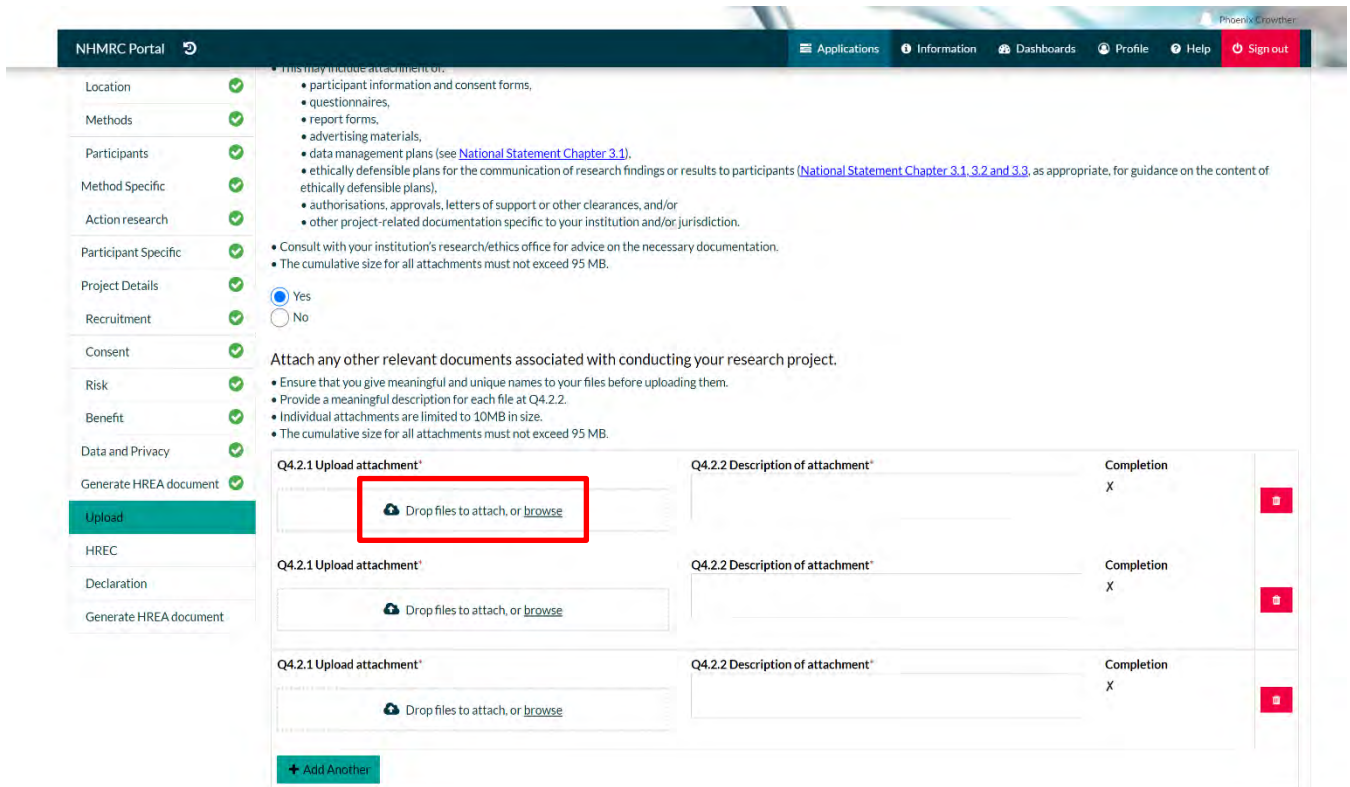
5. Select the file for attachment and select 'Open'.

6. Ensure the correct filename is listed and select 'Start upload'.

7. Confirm the correct document has been uploaded. The attached document is a copy of the original document. The original document will remain on your computer.

8. Add the description of the attachment. When a document has been successfully uploaded and the description added, the 'Completion' field changes from a cross to a tick.

9. To remove an incorrect attachment, select the X on the left side of the file name.

   To remove a row in the attachments table altogether (whether a document is attached or not), select the Delete button (rubbish bin) on the right side of the Completion field. The attachment will be removed from your application, but the original will remain on your computer.

10. **Note:** Please avoid uploading large files (e.g. uncompressed photos) to the HREA. Your application may not open if you have attached files with a cumulative size of 100MB or more.

2.5 How to attach an investigator's declaration

The HREA will automatically generate a declaration for each person listed in the 'Project Team' section. These can be signed by either attaching a digital signature, signing on screen or printing a blank space for a 'wet ink' signature.

1. Navigate to the 'Declarations' page and select 'Upload other evidence'. Then select 'Browse' to upload your file.

2. The HREA will open the file explorer on your computer. Select the file for attachment and select 'Open'.
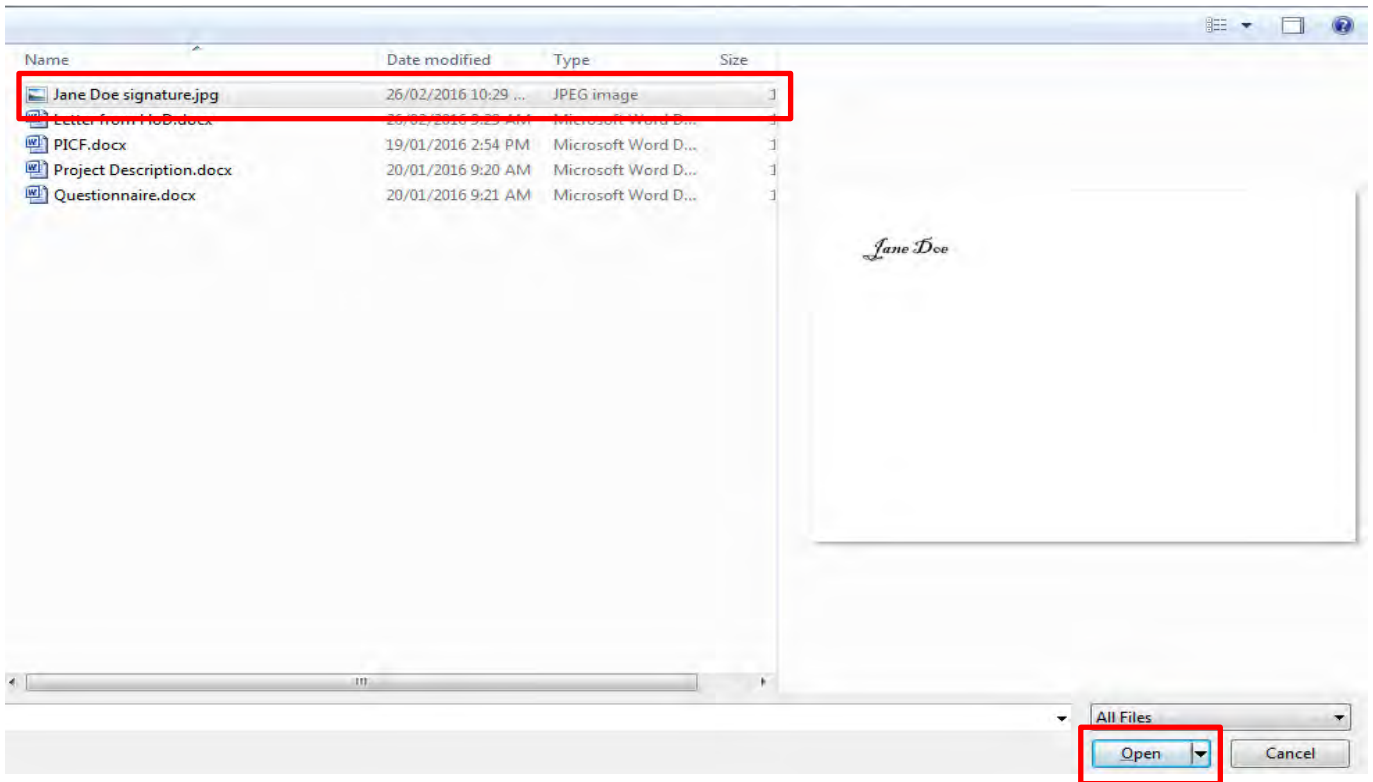
3. Ensure the correct filename is listed and select 'Start upload'.
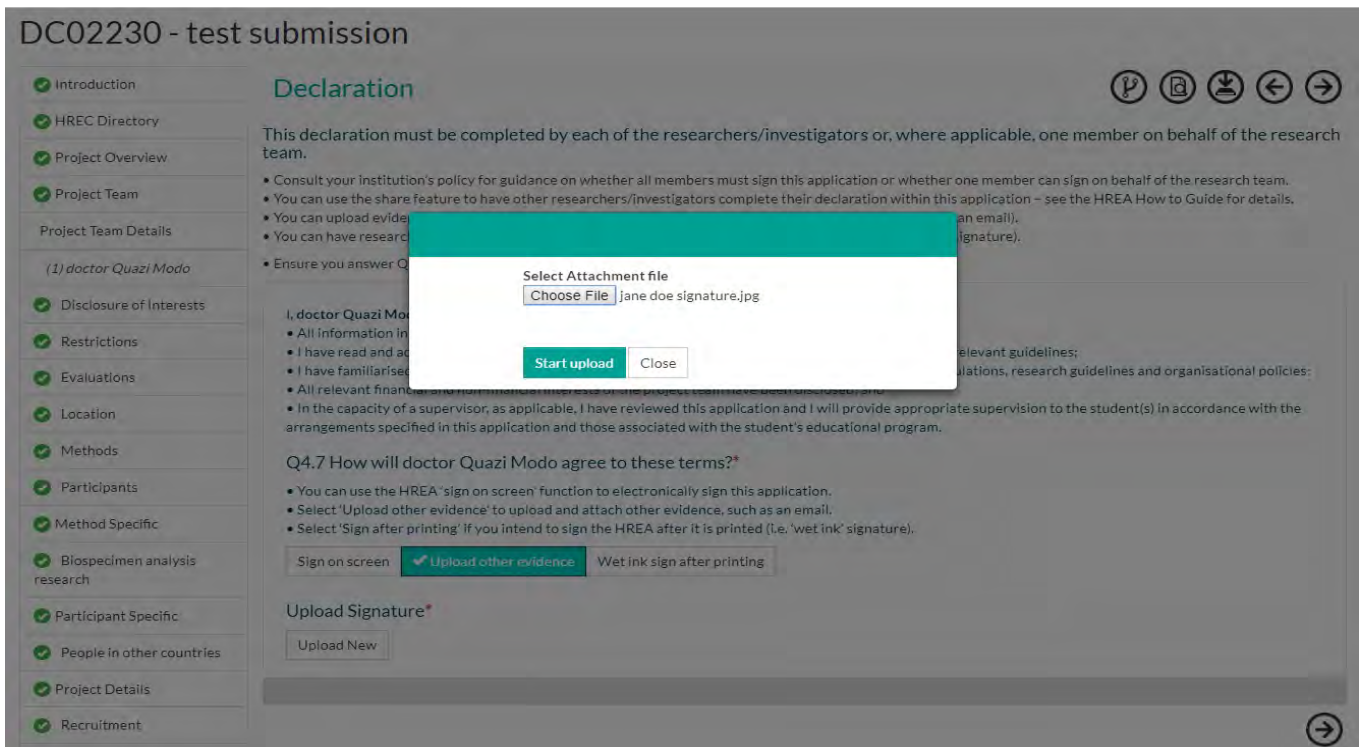
4. Confirm the correct file has been uploaded. Selecting 'Open' will download and open the attached document. The attached document is a copy of the original document. The original document will remain on your computer.

5. To remove the attached file, select the X on the left side of the file name.

2.6 How to sign on screen

1. Navigate to the 'Declarations' page and select 'Sign on screen'.

2. Sign in the box using the mouse or finger/stylus if using a touchscreen or tablet. Use the 'Clear' button (two arrows in the shape of a circle) to clear the signature box and start again.

2.7 How to wet ink sign

1. Navigate to the 'Declarations' page and select 'Wet ink sign after printing'.

2. Complete the rest of the HREA, generate the HREA document and print the form.

3. Sign the HREA form on the 'Investigator Team Declarations' section on the printed form.

3 Submitting and revising your ethics application
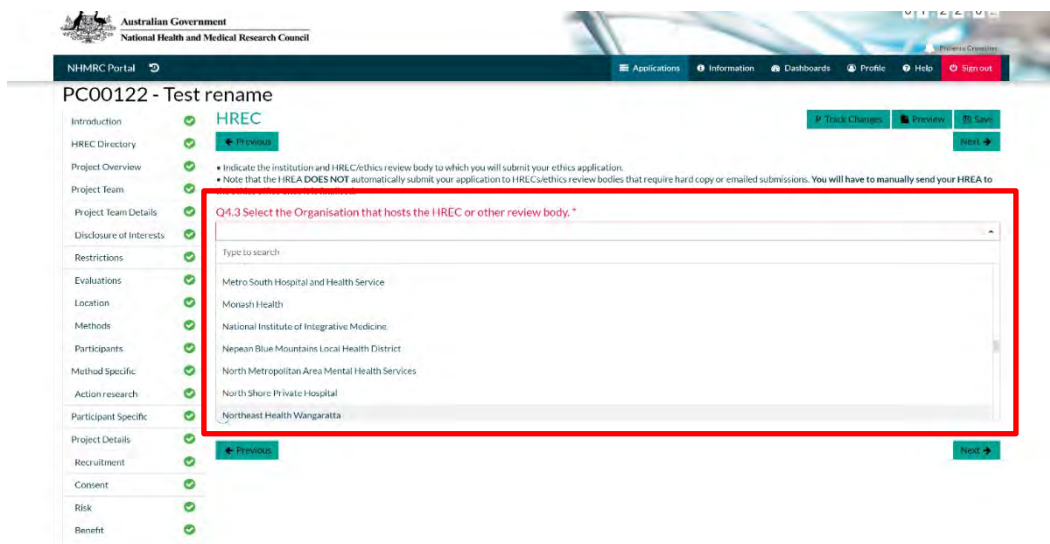
3.1 How to finalise and submit your application

1. Once you have completed all other application questions, navigate to Q4.3 on the 'HREC' page.

2. Use the drop-down menu to select the Organisation that hosts the HREC (or other ethics review body) to which you wish to submit your application. If you are unsure which Organisation to choose, contact your institution's ethics/research office for advice.

3. Selecting an Organisation will generate a list of HRECs (and/or other ethics review bodies) hosted by that Organisation. At Q4.4, select the HREC (or other ethics review body) to which you wish to submit your application. If you are unsure which HREC or Organisation to choose, contact your institution's ethics/research office for advice.

4. Contact information for Organisations and HRECs (or other ethics review body) can be found in the HREC Directory.

5. Select the review pathway under which you intend your application to be considered. Note that not all Organisations have separate review pathways, and that the institution to which you applying will review your application and determine the level of risk of the research project. Your answer to Q4.5 will only inform them of the intended review pathway.

6. Navigate to the 'Generate HREA document' page.

7. Verify that the application is complete and the Project Description/Protocol and any other documents have been attached. Completed sections are marked with a tick symbol.

8. If the form is incomplete, you will not be able to submit it until all the mandatory questions have been completed. Incomplete questions will show a validation error at the top of screen and incomplete sections are marked with a cross symbol.

9. Once the form is complete, select 'Generate HREA document'.
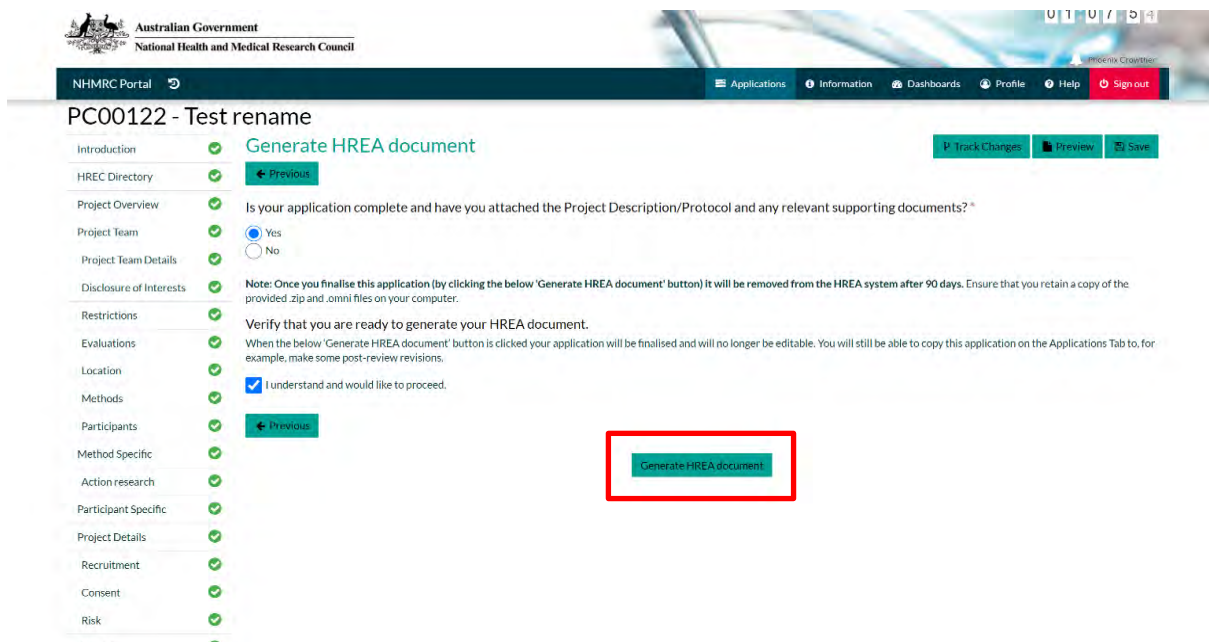
10. The 'Application submission' dialogue box will open, where you can download your HREA files. Download **all** the files by clicking on each link.

The .zip file contains .pdf and .rtf versions of your application, along with any documents you have attached. Note that the .pdf and .rtf files **cannot** be uploaded into the HREA if they need to be amended.

The .omni file is a file type unique to the HREA. It allows the completed application to be re-uploaded to make any amendments required by the HREC or to use the completed application as the basis of a new application in the future.

Note: the 'tracked changes' .docx file will only appear if you have created a 'tracked changes' version. See **3.4 How to view a revised application with changes highlighted.**
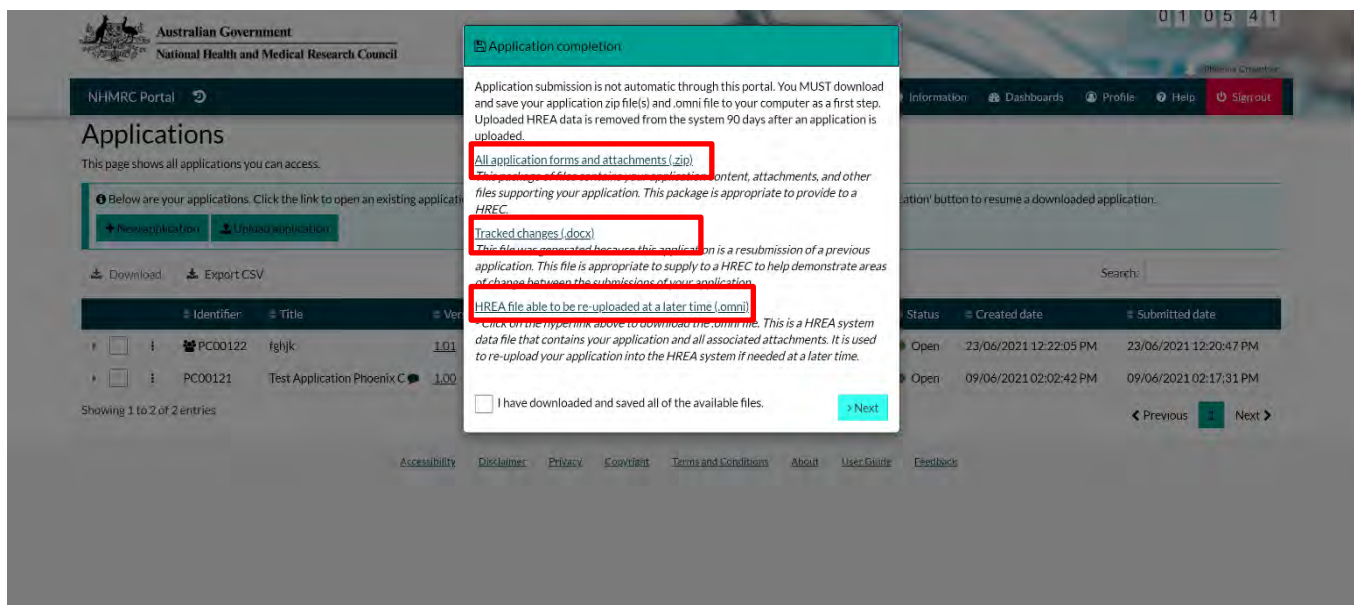
You must download both the .omni file and the .zip file/s and save them in a safe place.

You must ensure you have saved all the files you need before closing this dialogue box.

Completed applications and data is removed from the HREA system after 90 days.

11. Once you have downloaded all the files you require and have confirmed they have been saved, tick the confirmation box and select 'Next'.
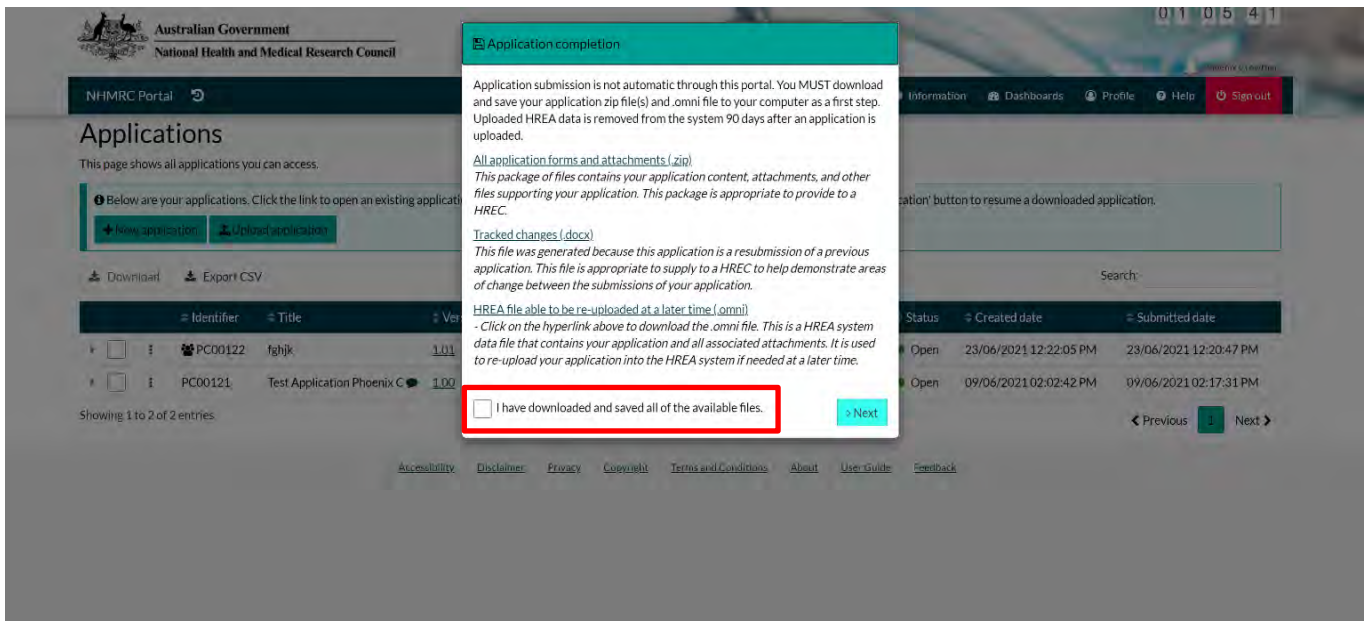
12. A dialogue box will be displayed that shows how your chosen HREC wishes to receive the application. Follow the instructions provided to submit your application. You will also receive an email at your preferred contact email address with these instructions.

The HREC/institution to which you are applying determines their preferred method of submission.

Note: If you have any questions about the HREC/other ethics review body submission process, you should contact the HREC using the contact details provided or the institution's ethics/research office.

13. If you need to re-download the .zip and/or .omni files, select 'Back' and download the files. To finish your session, select 'Close'.

Note: It is strongly recommended that you confirm all the files you require have been downloaded and saved before closing the session.

3.2 How to revise and resubmit a previously submitted application

HRECs or other ethics review bodies will often require an application to be revised and resubmitted following an initial review. A previously submitted application can be opened and amended within the HREA for resubmission.

For HREA users, completed applications are stored in the HREA for 90 days. If more than 90 days have passed, the completed application .omni file will have to be uploaded to the HREA.

If you need to upload a previously downloaded .omni file:

1. Navigate to the 'Applications' page and select 'Upload application'.
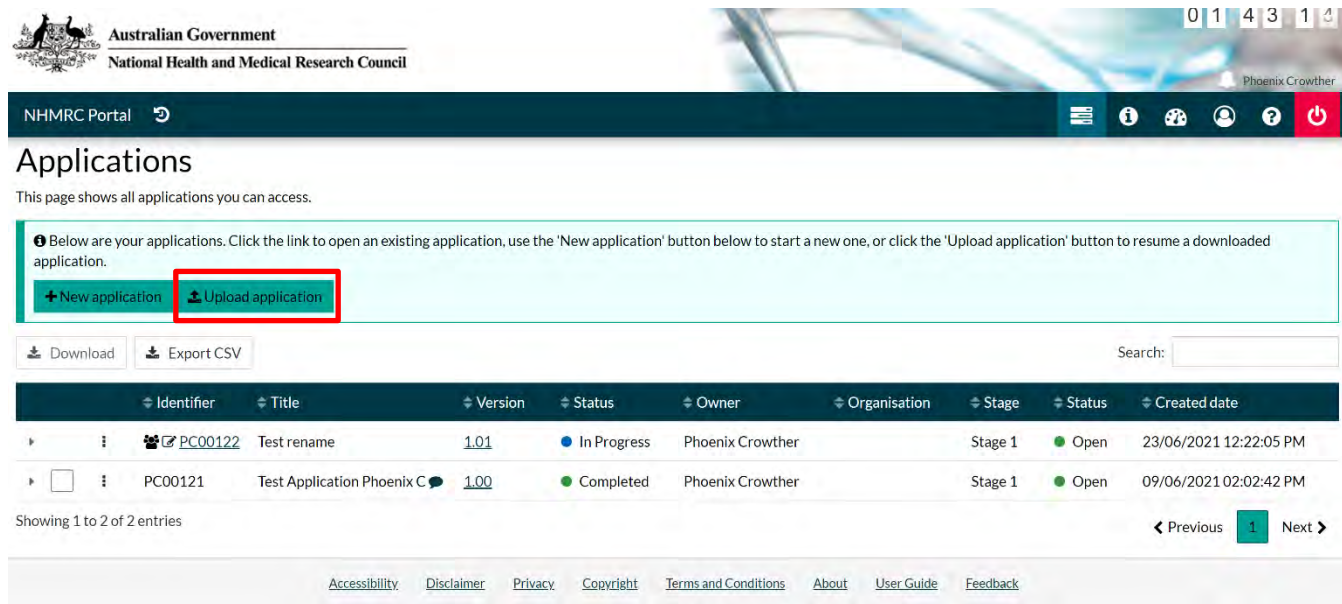
2. Navigate to the .omni file you saved on your computer for the application you wish to upload and select 'Open'. Once the file opens, it should then appear in your Applications list.
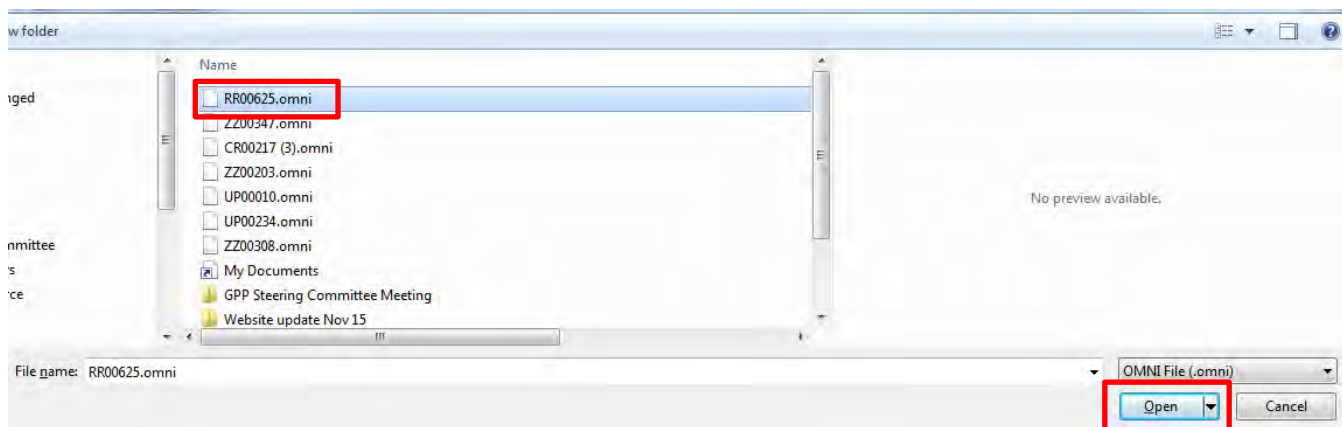
If the completed form is still listed in the HREA Applications list:

1. Navigate to the 'Applications' page and expand the menu by selecting the 'Options' button (three dots on the left side of the Identifier) next to the completed application you want to revise.

2. In the 'Options' menu, select the 'New version' button.

3. Once you have selected 'New version', a dialogue box will ask you if you want to create a new version of an existing application or to copy an application instead.
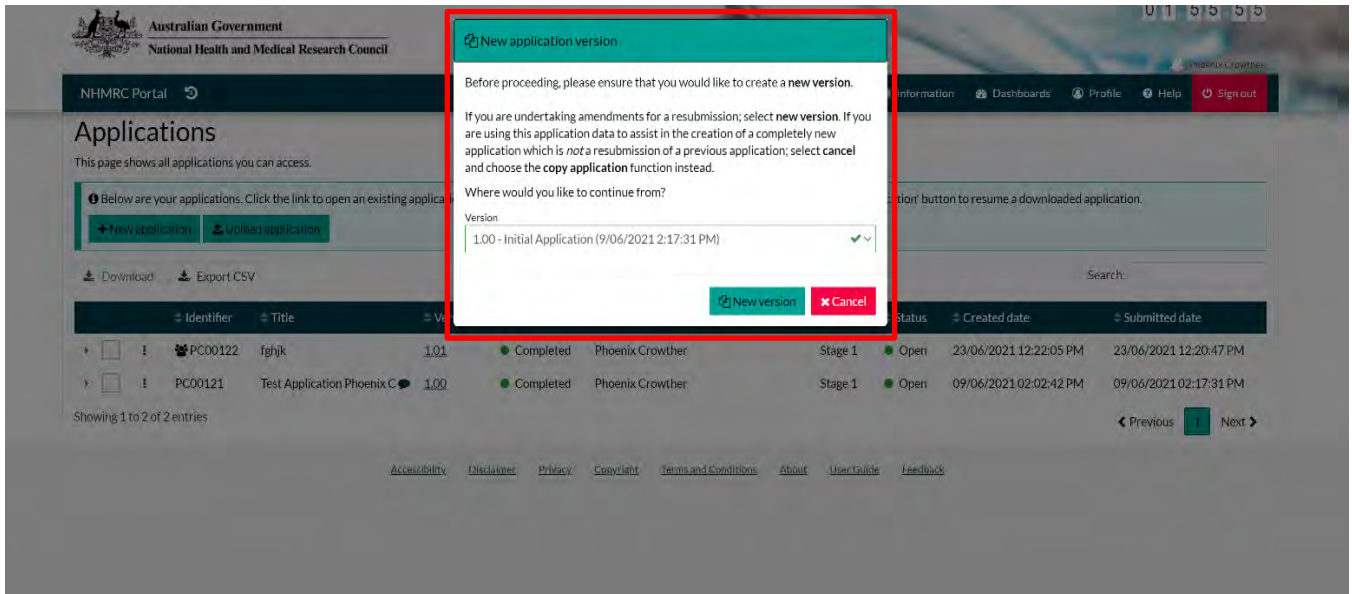
3. Select 'New Version' to create a new version of your application. If you want to copy your application, see **3.3 How to use an existing application as a template for a new application.**
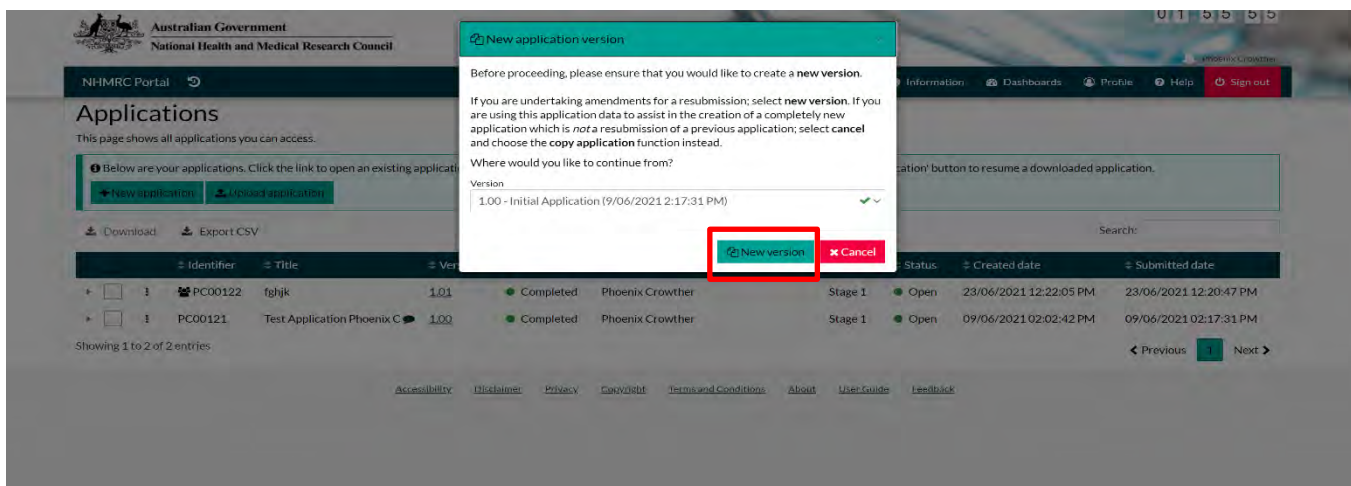
4. Enter the title of the new version of the application, enter any application comments and then select 'New Version'.
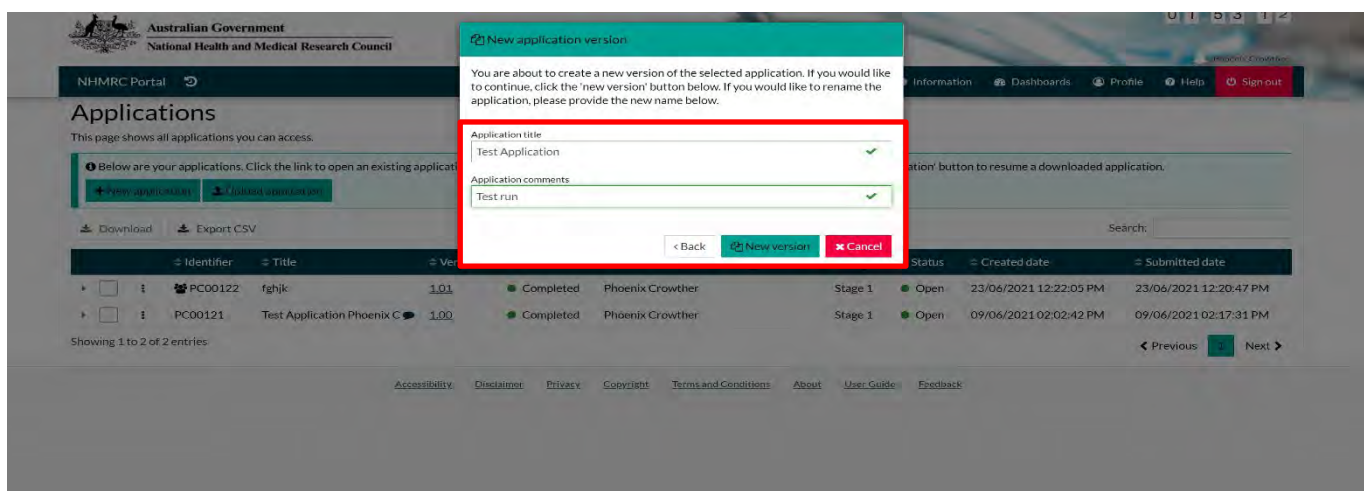
5. The new version will be added to your Applications list.

6. The new version can now be opened, reviewed and edited. Note that when a new version of an existing application is created (whether that existing application has been submitted or not) a copy with changes highlighted can be downloaded. Selecting the 'Track Changes' button will generate a version of your application with changes between the previous version and the new version highlighted in coloured font.

See **3.4 How to view a revised application with changes highlighted** for further information on generating and viewing tracked changes versions of applications.

Note: The new version/amend/submit process can occur as many times as necessary.

3.3 How to use an existing application as a template for a new application

The 'Copy application' function can also be used to generate a template for a new application from a completed application or another in-progress application. For example, if you regularly make applications with the same investigator team you could create a template that contains all their information, avoiding the need to enter it every time you create an application. There are two options available:

a) If required, upload the .omni file of a completed application from your computer.

b) Create a copy within the HREA if it is less than 90 days since your application was completed. To copy within HREA, perform the following steps.

1. Navigate to the 'Applications' page, identify the application you wish to share and select the 'Options' button (three dots on the left side of the Identifier) next to it.
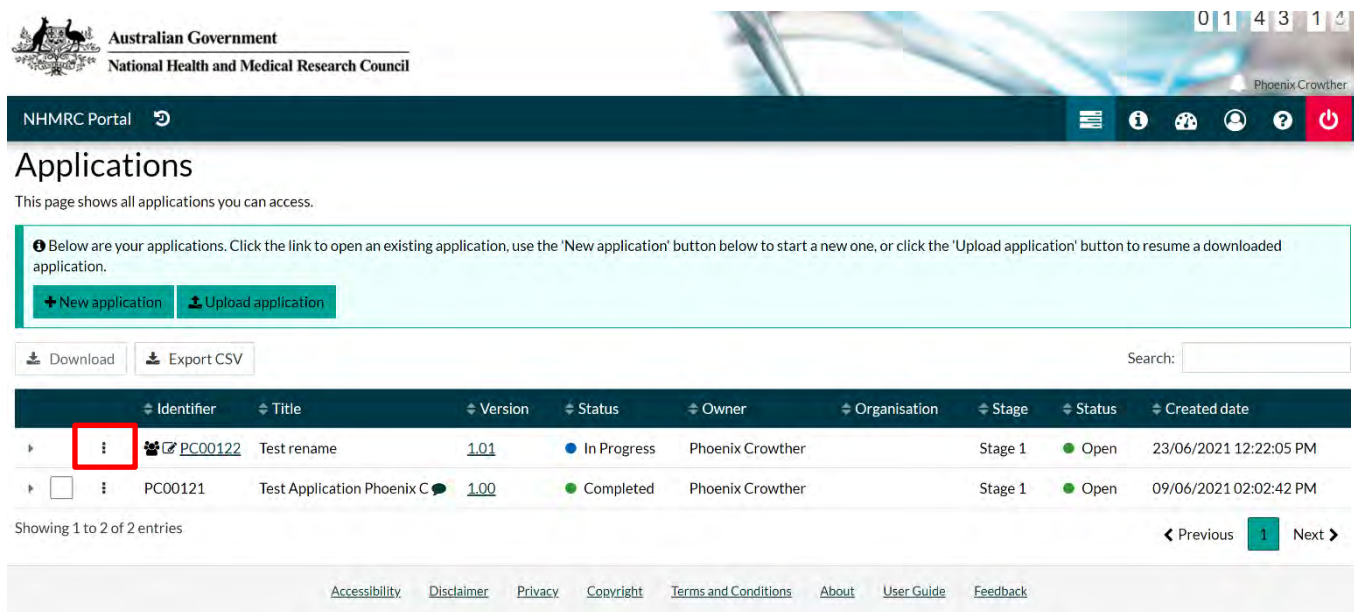
2. Select the 'Copy application' button.
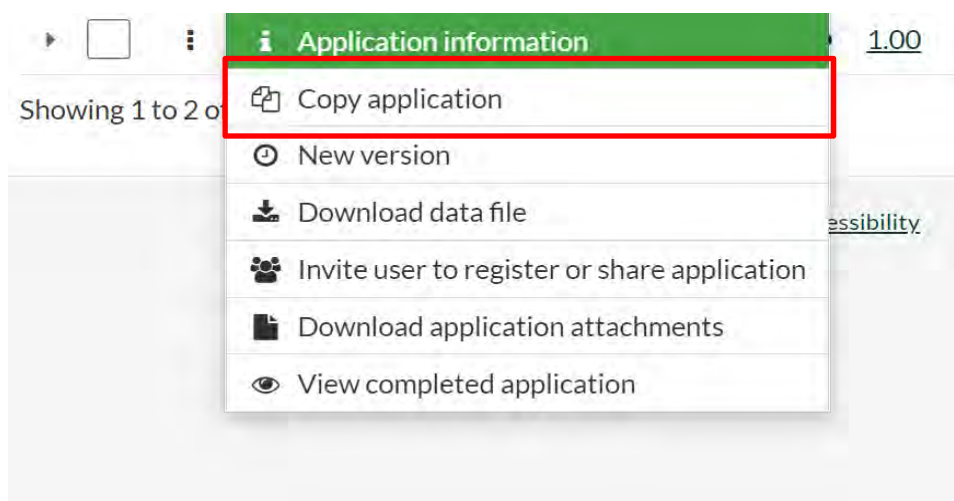
3. Select 'New application'.
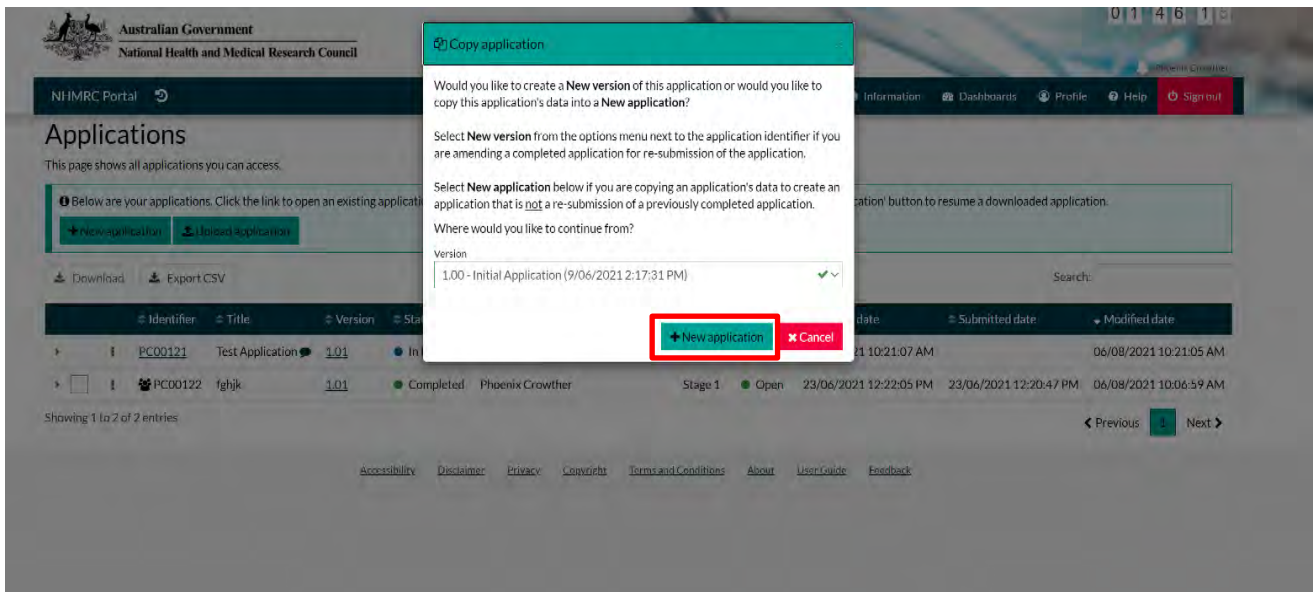
4. Enter the title of the new application and select 'New application'.
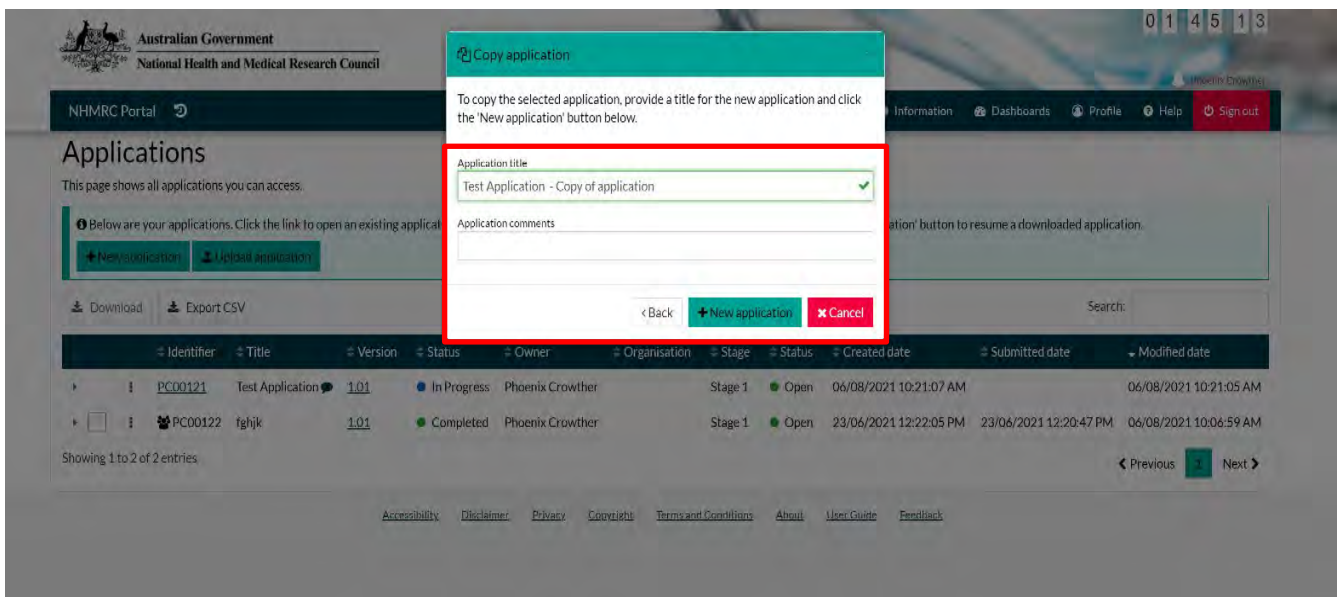
5. The new application will be added to your Applications list. Open the new application and remove all the 'non-template' information.

   Note: It is strongly recommended that any templates you create are saved locally on your computer as .omni files, as inactive incomplete applications will be removed from the HREA after a period of 365 days.

   Alternatively, you can start a new application, partially compete it as appropriate and use this as a template for future applications. As above, it is recommended that any templates are saved on your computer as .omni files, as inactive incomplete applications will be removed from the HREA after 365 days.

3.4 How to view a revised application with changes highlighted

The HREA includes a feature to generate a 'tracked changes' version of a revised ethics application. This can be used to review any changes at any time when a revised application is in progress, and may also be requested by the HREC or other ethics review body when submitting a revised application.

1. Create a 'New version' of an application. See **3.2 'How to revise and resubmit a previously submitted application'** for details on how to do this. Ensure you name the new version appropriately in order to keep track of multiple versions of an application.

2. Revise the new version as appropriate. You can generate a .docx version of the draft application highlighting any changes at any time by selecting the 'Track Changes' button.

2. The .docx document shows the changes made to the draft application in coloured text.

Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the National Statement.
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

Project Overview

Project title:

Investigation of the consumption of dark chocolate on hthe happiness of PhD students

Summary of the research project:

In this project we will ask 50 people100 PhD students to eatconsume dark chocolate. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse at iaculis tellus, eget blandit turpis. Nullam malesuada interdum tincidunt.

Location/s where the research will be conducted:

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse at iaculis tellus, eget blandit turpis. Nullam malesuada interdum tincidunt. Vestibulum vitae sollicitudin lorem. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos himenaeos. Integer auctor lobortis orci vel mattis.

Funding for the research project:

dfd

3.5 How to submit a revised version of an application to an HREC

The process for submitting a revised version of an application is the same as the initial submission. However, you will also have the opportunity to download a 'tracked changes' version of the revised application.

1. Follow the instructions at **2.3.1 How to finalise and submit your application** to submit your HREA to the HREC (or other review body) and download your application for your records up to the point where the 'Application submission' dialogue box opens. The dialogue box will include the option to download a 'tracked changes' version of the application:

2. Once the documents you require have been downloaded, continue to submit your revised application as per the requirements of the HREC. Note: the 'tracked changes' version downloaded here will not be watermarked as 'Draft'.

   Note: You must download the .omni file, the .zip file and the tracked changes .docx file and save them in a safe place on your computer.

   Ensure you have saved all the files before moving from this page.

3.6 How to access your files after submission

As outlined above, you should download all the files you need and save them in a safe place on your computer. However, if you need to access your files after submission, they are available on the Applications page for 90 days.

You must not rely on the HREA to store your submitted or completed applications – always download and save your applications on your computer as you would for any important document.

1. Navigate to the 'Applications' page.

2. Identify the application you want to download. Select the 'Options' button next to that application to expand the menu (three dots on the left side of the Identifier).

3. To download the .omni file (which can be re-uploaded into the HREA to create a new version or a template for a new application), select 'Download data file'. The .omni file will be downloaded to your computer's default downloads folder.
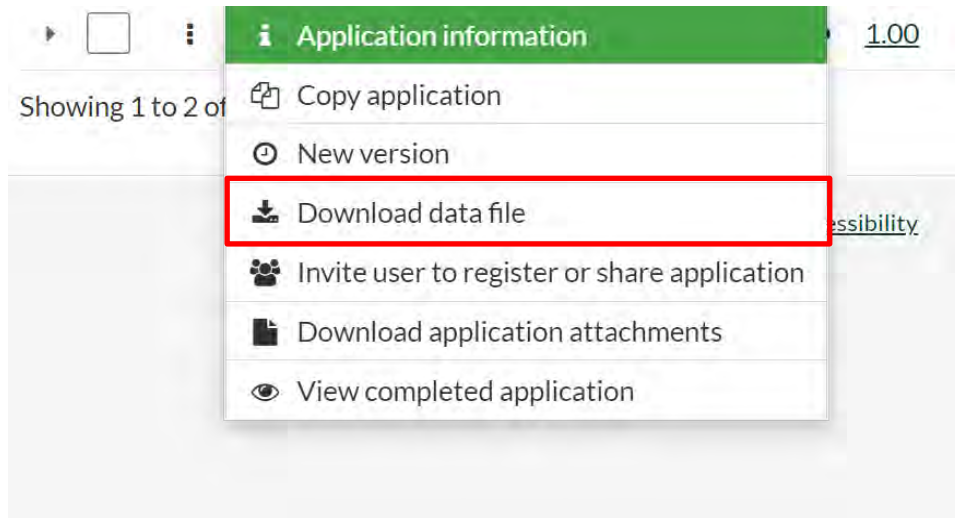
4. To download the .zip file (which contains the .pdf and .rtf version of your application along with any attachments you included in your HREA) select the 'Download application attachments' button.
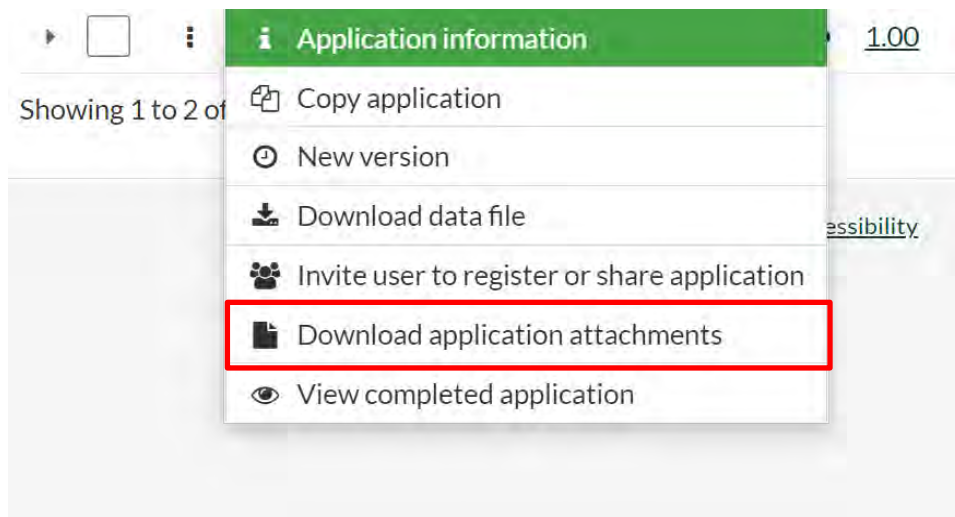
5. From the dialogue box that opens, select the .zip file labelled 'All application forms and attachments'. If this is an amended application, you will also see an option to download a 'tracked changes' document.
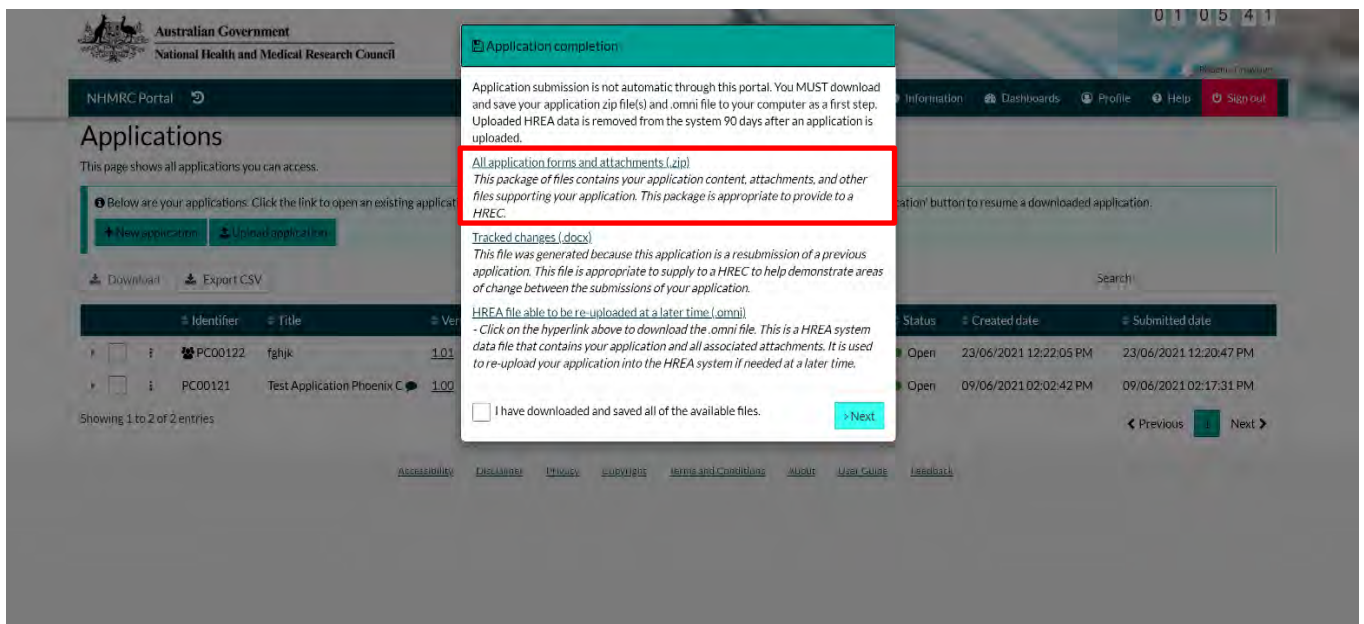
6. The .zip file will be downloaded to your default downloads folder and appear at the bottom of screen.