Human Research Ethics Application (HREA)
‘How to’ Guide

March 2018
Version 3.0
## Contents

1. Introduction ......................................................................................................................................................................................... 3

2. How-to guide ............................................................................................................................................................................................ 4

   2.1 Creating and managing your HREA account ...................................................................................................................................... 4

      2.1.1 How to create a new account .................................................................................................................................................. 4

      2.1.2 How to sign in with your registered account ........................................................................................................................... 6

      2.1.3 How to reset a forgotten password .......................................................................................................................................... 7

      2.1.4 How to manage your profile ..................................................................................................................................................... 9

      2.1.5 How to change your username ............................................................................................................................................... 11

      2.1.6 How to change your password ............................................................................................................................................... 17

      2.1.7 How to access the HREA as a Guest ....................................................................................................................................... 19

   2.2 Creating your ethics application .................................................................................................................................................. 20

      2.2.1 How to start a new application ............................................................................................................................................... 20

      2.2.2 How to share your application with collaborators .................................................................................................................... 22

      2.2.3 How to attach the Project Description/Protocol ..................................................................................................................... 27

      2.2.4 How to attach other relevant documentation .......................................................................................................................... 31

      2.2.5 How to attach an investigator’s declaration ........................................................................................................................... 36

      2.2.6 How to sign on screen ............................................................................................................................................................ 39

      2.2.7 How to wet ink sign ............................................................................................................................................................... 40

   2.3 Submitting and revising your ethics application .......................................................................................................................... 41

      2.3.1 How to finalise and submit your application .......................................................................................................................... 41

      2.3.2 How to revise and resubmit a previously submitted application ............................................................................................ 49

      2.3.3 How to use an existing application as a template for a new application ............................................................................... 53

      2.3.4 How to view a revised application with changes highlighted ................................................................................................ 55

      2.3.5 How to submit a revised version of an application to an HREC ............................................................................................ 57

      2.3.6 How to access your files after submission ............................................................................................................................ 58

3. Troubleshooting .................................................................................................................................................................................. 61
1 Introduction

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

It is recommended that, before using the HREA, you review the HREA Getting Started guide, available at https://www.nhmrc.gov.au/health-ethics/human-research-ethics-application-hrea/hrea-support? which outlines the fundamentals of the HREA. These include the principles behind the form, how to manage your applications, how to navigate the HREA and how to enter information.

There are also a series of ‘how-to’ videos that walk you through many of the activities in this document. These are available at https://www.nhmrc.gov.au/health-ethics/human-research-ethics-application-hrea/hrea-support?

If you have any questions please contact HREA help at help@hrea.gov.au or 1800 500 983 (international callers +61 2 6217 9451) Monday to Friday 09:00 a.m. to 05:00 p.m. AEST/AEDT, excluding public holidays and ACT public holidays.
2 How-to guide

2.1 Creating and managing your HREA account

2.1.1 How to create a new account

Navigate to https://hrea.gov.au/ with a web browser and click the sign in button.

1. Select ‘Sign up 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. Help on using the reCAPTCHA (a Google resource to prevent malicious software) is available here: https://support.google.com/recaptcha/?hl=en.
3. Click the ‘Register’ button

4. You will receive an email confirming your registration with a web link included. Click on this web link to activate your account. If you don’t 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 instructions below.
2.1.2 How to sign in with your registered account

Navigate to https://hrea.gov.au/ with a web browser and click the sign in button.

1. Enter your username (the email address used for registration) and password on the sign in page then select ‘Sign in’.

![Sign in page]

2. Click ‘Agree’ to accept the licence agreement and enter the HREA.

![Licence Agreement]

Your use of this system is subject to NHMRC’s Terms and Conditions. You must only use this system and any associated personal or institutional account for lawful purposes and in a manner that does not infringe the rights of, or restrict or inhibit the use and enjoyment of, the service by any third party. This includes conduct which may harass or cause distress or inconvenience to any person or disruption to the system. By continuing to use this system you acknowledge that you are aware of and agree to these Terms and Condition. Use of this system is monitored at all times by NHMRC staff.
2.1.3 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. Click on ‘Set password’.

7. If you have successfully reset your password you will see the below notification.
2.1.4 How to manage your profile

1. Sign in to the HREA with your registered account.

2. Select the ‘Profile’ button on the HREA front page.

3. Select the profile component to modify from the left hand menu. The options are Personal details, Address details, Phone details and Email details.
4. Amend details and select ‘Save’
2.1.5 How to change your username

1. Sign in with your registered account.

2. Select ‘Profile’ button on HREA front page.

4. Select ‘Change username’.

5. Enter your password and the new username and select ‘save’. Note that the username must be an active email address. Do not leave the HREA after clicking ‘save’.
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 format.

6. An email will be sent to the original email address with a web link for you to verify the change to the username.
7. The change to the username will be verified on-screen.

8. Enter the new username and password to confirm the change has occurred.
9. To make sure that emails are now sent to your new username, select the ‘Profile’ button on the HREA front page.

10. Select ‘email details’.

11. Select ‘Add new email address’.

12. Enter the new email address (your new username), tick ‘preferred’ and select ‘save’.
2.1.6 How to change your password

1. Sign in with your registered account.
2. Select ‘Profile’ button on HREA front page.
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.
2.1.7 How to access the HREA as a Guest

Navigate to www.hrea.gov.au with a web browser and click the sign in button.

1. Select ‘Guest Access’.

2. Click ‘Agree’ to accept the licence agreement and enter the HREA.
2.2 Creating your ethics application

2.2.1 How to start a new application

1. Log in to the HREA as a registered user (recommended) or as a guest.

2. Select the ‘New application’ button

3. Select ‘Human Research Ethics Application’
4. Enter an Application title and any comments you want to include and click ‘Done’. **Caution:** Please avoid using apostrophes in your application title.

5. This will take you to the first page of the HREA. From here you can answer HREA questions and complete your application.
2.2.2 How to share your application with collaborators

The HREA allows you to easily 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 application.

1. Navigate to the Applications page

![Application page]

2. Identify the application you wish to share and click on the button next to it.

![Application page with selected application]
3. Click on the button.

4. Enter the username (i.e. the email address) of the person you wish to share the application with. They will be added to the list of assigned users. Tick the ‘Share’ box and select from either the ‘View’ or ‘Edit’ option. ‘View’ will allow the user to open the application but not make any alterations to it. ‘Edit’ will allow the user to open and edit the application.
5. Click on the Save button.

6. The person with whom you have shared the application will receive an email. If the person does not have a registered HREA account, they will be prompted to create one.
7. The icon indicates an application is being shared.

8. Note that only one person can edit a shared application at a time.

9. To ‘unshare’ an application, identify the application you wish to ‘unshare’ and click on the button next to it. Please note that only the form owner can ‘unshare’ an application.
10. Click on the **Invite user to register or share** button.

11. Identify the user/s you wish to remove and click on the **Delete** button.
12. Deleted users will no longer appear in the Assigned Users list. Click ‘Save’ to complete and return to the ‘Applications’ list screen.

13. Note: If you share an application with another user and grant them ‘edit’ permission then they will be able to complete the application on your behalf.

14. 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.
2.2.3 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 the Upload page and select the ‘Upload New’ button.

2. Select ‘Choose file’ – the HREA will open the file explorer on your computer.
3. Select file for attachment and select ‘open’.

4. Ensure correct filename is listed and select ‘Start upload’
5. Confirm the correct document has been uploaded. Selecting ‘Open’ will download the attached document. The attached document is a copy of the original document. The original document will remain on your computer.

6. To remove the attached Project Description/Protocol, select ‘Clear content selection’.

7. **Caution**: 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.
2.2.4 How to attach other relevant documentation

As other documents attached here are not mandatory, and there may be more than one, the process for attaching other relevant documents is slightly different to the process for attaching the mandatory Project Description/Protocol.

1. Navigate to the Upload page
2. Click ‘Yes’ to show the upload attachment and attachment description fields.

3. To add more attachments, click the button. In this example, three rows have been added in order to add three separate attachments.
3. To add an attachment, select the ‘Upload New’ button next to the row.

4. Select ‘Choose file’ – the HREA will open the file explorer on your computer
5. Select file for attachment and select ‘open’.

![Select file screenshot]

6. Ensure correct filename is listed and select ‘Start upload’.

![Start upload screenshot]
7. Confirm the correct document has been uploaded. Selecting ‘Open’ will download the attached document. The attached document is a copy of the original document. The original document will remain on your computer.

8. Add the attachment description. When a document has been successfully uploaded the ‘completion’ field changes from X to √.
9. To remove a row in the attachments table (whether a document is attached or not), select the square next to the row to be removed and click the button. The attachment will be removed from the HREA, but the original will remain on your computer.

10. **Caution:** 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.

### 2.2.5 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 either by attaching a digital signature, signing on screen or printing a blank space for a ‘wet ink’ signature).

2. Once the document browser window opens, choose the file and select 'Open'.
3. Ensure correct filename is listed and select ‘Start upload’

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

5. To remove attached evidence, select ‘Clear content selection’.
2.2.6 How to sign on screen

1. Navigate to ‘Declarations’ page and select ‘Sign On Screen’.

2. Sign in the box using the mouse (or finger if using a tablet). Use the ‘Clear’ button to clear the signature box and start again.
2.2.7 How to wet ink sign

1. Navigate to ‘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 on the ‘Investigator Team Declarations’ section.
2.3 Submitting and revising your ethics application

2.3.1 How to finalise and submit your application.

The method by which your application is submitted is determined by the institution to which you are applying, and the HREA will inform you how to submit the application.

1. Once you have completed your application, navigate to the HREC page.

2. Use the pull down list to select the Organisation that hosts the HREC (or other ethics review body) you wish to submit your application to. If you are not sure which Organisation to choose you should contact your institutional ethics office for advice.
3. Selecting an Organisation will generate a list of HRECs (and/or other ethics review bodies) hosted by the Organisation. Select the HREC (or other ethics review body) to which you wish you want to submit your application. If you are not sure which HREC to choose you should contact your institutional ethics office for advice.

4. Contact information for the selected HREC or ethics review body will be displayed.
5. Select the review pathway you intend your application to be considered under. Please note that not all Organisations may 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 this question will only inform them of the intended review pathway.
7. Verify that the application is complete, the Project Description/Clinical Trials Protocol has been attached and that it is ready to be generated. Select ‘Generate HREA document’.

8. If the form is incomplete you will not be able to submit it until all the mandatory sections have been completed. Incomplete sections are marked with a 📝 symbol.
9. Once the form is complete, select the ‘Generate HREA document’ button. Note that all the mandatory sections have a green ✔️ beside the heading, indicating that they have been completed.

10. The ‘Download files’ dialogue box will open. Download all the files by clicking on the links. 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 unique file type to the HREA, and allows the competed application to be easily re-uploaded to make any amendments required by the HREC, or to use the submitted application as the basis of a new application in the future.

You must download both the .omni file and the .zip file/s and keep them in a safe place.

Submitted application data is removed from the HREA system after 90 days.

You must ensure you have all the files you need before moving from this page.
11. Once you have downloaded all the files you require and have confirmed they have been downloaded, select ‘I have downloaded and saved all of the available files’ and select ‘Next’.

12. You will be notified as to how your chosen HREC wishes to receive the application, e.g. post or email. Follow the instructions provided to submit your application. In the example below, the HREC only accepts applications via email. You will also receive an email at your preferred contact email address with these instructions.

If you have any questions about an individual HREC/review body submission you should contact the HREC/review body using the contact details provided.
13. In the final example, the HREC only accepts applications via web service. Unlike the previous submission methods, where the applicant will have to print and post or email the application as required by the HREC, no further action on behalf of the applicant will be required. The HREC will be notified that an application is available for collection from the NHMRC’s server and they will then download that application.

Note: If your ethics committee (or its portal) has not confirmed that they have received your application within 48 hours, you should contact them about your application.

15. To finish your session, click ‘Close’. If you need to re-download the .zip and/or .omni files, click ‘Back’ and download the files.

It is strongly recommended that you confirm all the files you require have been downloaded before closing the session.
2.3.2 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 easily opened, amended and resubmitted within the HREA.

For registered users, submitted applications are stored in the HREA for 90 days. If longer than 90 days has passed, the previously submitted application .omni file will have to be uploaded.

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

1. Navigate to the Applications page and select ‘Upload application’.

   ![Applications page](image1)

   2. Navigate to the .omni file on your computer for the application you wish to upload and click ‘open’.

   ![File Explorer](image2)
If the previously submitted form is still listed in the HREA applications list:

1. Navigate to the Applications page and expand the menu by clicking on the button next to the submitted application you want to revise.
2. Select the ‘New Version’ button.
3. Once you have selected ‘New Version’ you will see the following dialogue box that will ask you if you want to create a ‘New application’ or a ‘New version’.

5. Enter the title of the new application and enter application comments then select ‘New Version’.

6. The new version will be added to your Applications list.

7. The new version can now be opened, reviewed and edited. Note that, when a new version of an existing application (whether that existing application has been submitted or not) a copy with changes highlighted can
be downloaded. Selecting the button will generate a pdf version of your application with changes between the previous version and the current version highlighted. See below for further information on generating and viewing tracked changes versions of applications.

The submit/new version/amend/submit process can occur as many times as necessary.
2.3.3 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 previously submitted 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 2 options available:

a) If required, import the .omni file of a previously submitted application from your computer.

b) Create a copy within HREA if your completed application is under 90 days since it was completed. To copy within HREA perform the following:

1. Navigate to the ‘Applications’ page, identify the application you wish to share and click on the button next to it.

2. Click on the ‘Copy Application’ button
3. Select ‘New Application’.

4. Enter the title of the new application and select ‘New application’. **Caution:** please avoid using apostrophes in the Application title.

5. The new application will be added to your Applications list. Note: the version number is now numbered as 2.

Open the new application and remove all the ‘non-template’ information. It is strongly recommended that all templates are stored locally on your computer as .omni files, as inactive applications will be removed from the HREA after a period of 365 days.

Alternatively, you can start a new application, partially complete it as appropriate and use this as a template for future applications. As above, it is recommended that any templates are stored on your computer as .omni files, as inactive applications will be removed from the HREA after 365 days.
2.3.4 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 easily review any changes, and may also be requested by the HREC or other ethics review body when submitting a revised application.

1. Create a ‘new version’ of a previously submitted application. See ‘Revising and resubmitting a previously submitted application’ for details on how to do this. Ensure you name the new version appropriately to keep track of multiple versions of an application.

2. Revise the new version as appropriate. You can generate a PDF of the draft output document highlighting any changes at any time by selecting the button.
3. Selecting the button will generate a PDF download with changes highlighted. This pdf version will be watermarked as ‘Draft’.

4. Open the .pdf file.

The PDF document shows the changes made to the application as red text.
2.3.5 How to submit a revised version of an application to an HREC

The process for submitting a revised version of a previously submitted 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 to submit your HREA to a Human Research Ethics Committee (or other review body) and download your application for your records up to the point where the ‘download files’ 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 pdf ‘Tracked changes’ version downloaded here will not be water marked as ‘Draft’.

You must download the .omni file, the .zip file and the tracked changes .pdf file and keep them in a safe place.

Ensure you have all the files before moving from this page.
2.3.6 How to access your files after submission

As outlined above, you should download all the files you need and keep them in a safe place. However, if you need to access your files after submission they are available on the Applications page. Submitted applications will only be held on the HREA system for 90 days.

You must not rely on the HREA to store your completed applications – always download and store 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. In this example the second application has been selected.
3. Select the button to expand the menu.

4. To download the .omni file (that can be re-uploaded into the HREA to create a new version or as a template for a new application) select the button. The .omni file will be downloaded to your default downloads folder.

5. To download the .zip file (that contains the PDF and RTF version of your application along with any attachments you included in your HREA) select the button.
6. From the dialogue box that opens, select the hyperlink ‘all application forms and attachments’.

If this is an amended application you will also see an option to download a tracked changes document.

7. The .zip file will be downloaded to your default downloads folder.
3 Troubleshooting

The HREA has undergone a comprehensive testing program, including a nationwide beta testing program with over 600 users taking part. Although the majority of users didn’t encounter any issues, some users reported problems in a number of areas. The following is a troubleshooting guide based on information obtained from the testing programs.

The vast majority of issues can be resolved by ensuring you are using the most up-to-date version of your web browser. NHMRC staff have found the Google Chrome works consistently for the HREA, but have also successfully used Internet Explorer, Firefox and Safari.

If your issue is not resolved by updating your browser and/or switching to Google Chrome, the following outlines how to resolve some reported problems.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Resolution</th>
</tr>
</thead>
</table>
| You have created an account, but not received an activation email after around 5 minutes. | 1. Check your junk/spam mailbox to see if the email has been redirected.  
2. If the email is not in the junk/spam mailbox, navigate to the sign-in page and select ‘Reset your Password’.  
3. In some cases, your institution’s firewall may delay or block emails from the HREA. If the steps do not work, reset your password and allow 30-60 minutes for the email to arrive. If the problem persists contact your institution’s IT section. |
| You see an error message you’re your application is ‘locked for editing’ by you. | 1. Log out, close your browser and log back in.  
2. If the issue persists, copy your application |
| I can’t open the .omni file I downloaded. | 1. The .omni file can only be opened in the HREA system. To upload the .omni file into the HREA press the ‘Upload Application’ button on the Application Tab and select the omni file on your computer. |
| You have clicked ‘New application’ and provided a title but the application doesn’t appear. | 1. Ensure your current web browser is updated.  
2. Use the latest version of Google Chrome |
| You can’t find your submitted application | 1. Ensure you are on the “Applications” page of the HREA portal  
2. If someone shared an application with you it will no longer be visible in your list of applications once they, you or another user with edit privileges completes and generates the form.  
3. Submitted applications are removed after 90 days. Follow instructions to upload the .omni file you generated when submitting the application. |

For technical assistance using the HREA contact the HREA Help Team at help@hrea.gov.au or 1800 500 983 (international callers: +61 2 6217 9451).