Human Research Ethics Application (HREA)
User Guide

Beta testing version

2 June 2016

Please note that this user guide is only valid for the beta version of the HREA, and should only be used by the institutions formally involved in the beta testing.

It will be subject to revision following the beta testing period
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1 Introduction

The Human Research Ethics Application (HREA) has been developed by NHMRC, under the guidance of the HREA Advisory Group, for the ethics review of human research by Human Research Ethics Committees (HREC) or other institutional human ethics review bodies.

Designed to be applicable for all human research, the content has been developed with the input of experts in human research ethics, including researchers in numerous fields and HREC chairs from across Australia. The HREA questions and guidance have been developed to prompt researchers to consider and address the principles of the National Statement on Ethical Conduct in Human Research (2007) (the National Statement) with respect to the research being proposed.
2 Overview of the HREA

2.1 Key Concepts and Features

2.1.1 Referencing a Project Description/clinical trials protocol

The principles of ethical conduct in human research outlined in the National Statement are respect for human beings, research merit and integrity, justice and beneficence. The HREA seeks information from researchers as to how these principles will be addressed in the context of the research they propose to undertake. To this end, every HREA application consists of the completed online form and the attachment of a Project Description or clinical trials protocol. Other relevant attachments, such as consent forms, may also be attached to the HREA. The Project Description or clinical trials protocol is a mandatory attachment that provides scientific background and context for the proposed research.

2.1.2 Ensuring only applicable questions are asked

By identifying the methods and participant groups being used in the proposed research, the HREA will ensure only relevant questions and guidance are presented to the applicant.

2.1.3 Making collaboration quicker and easier

Two or more users with registered accounts can easily share an ethics application with one another, streamlining the collaboration and review process. In conjunction with the sharing functionality, the HREA also supports electronic signatures, allowing all research team members, no matter where they are located, to easily sign and endorse the application.

2.1.4 Modern IT features

The HREA incorporates a suite of contemporary IT features to make preparing and submitting ethics applications as simple as possible. Rich text entry is available for most fields, which includes the ability to use dot points, numbered lists, bold/italic/underlined text, superscript/subscript text, scientific characters and symbols and run a spell checker.

The HREA is simple to navigate using the menu on the left hand side, which will highlights incomplete sections and allows the user to complete the application in any order.

The HREA can also compare two versions of an application and automatically generate a PDF document with ‘tracked changes’, allowing reviewers to quickly see where changes and amendments have been made.

2.1.5 Direct submission to HRECs

When supported by the HREC’s institutional IT systems, the HREA allows seamless digital transmission of the application (along with all supporting documentation) to the ethics office. If this functionality is not supported, the HREA is able to be submitted via hard copy or email, depending on the preference of the HREC.
## 2.2 Accessing the HREA


### 2.2.1 Guest User access vs Registered User access

Researchers may log into the HREA as either a Guest User or Registered User, provided an account has been set up. The differences between the two types of users are summarised below.

<table>
<thead>
<tr>
<th>Type of user account</th>
<th>Guest User</th>
<th>Registered User</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Storage of Data</strong></td>
<td>Guest Users' application data will only be held on the HREA server for a single session – i.e. the time that a researcher is currently in the HREA. Once they leave the HREA website, their application data will be cleared.</td>
<td>Registered Users' application data will automatically be stored on the HREA server. Application data will only be removed 30 days after an application is submitted or 365 days after an in-process (not submitted) application was created.</td>
</tr>
<tr>
<td><strong>Saving of applications</strong></td>
<td>Guest Users must save their applications (as .omni files) to their own computers or devices. This file can be re-uploaded into the HREA at any time to continue working on the application.</td>
<td>Registered Users will automatically save their applications to the HREA server and can choose to download their applications (as .omni files) to their own computers or devices. Applications saved to the HREA server will be accessible to respective Register Users once they log in.</td>
</tr>
<tr>
<td><strong>Profile</strong></td>
<td>Guest Users do not have a profile.</td>
<td>Registered Users have a profile and are able to manage their own profile information.</td>
</tr>
<tr>
<td><strong>Sharing of applications</strong></td>
<td>Guest Users cannot directly share applications within the HREA. To collaborate on an application, Guest Users will have to export and send the application (as a .omni file) outside of the HREA. Their colleagues will have to upload the .omni file into the HREA to review and edit the application.</td>
<td>Registered Users can invite colleagues to collaborate on their application within the HREA using the share function or can export and send the application outside of the HREA system. Registered Users who share an application in the HREA can manage who has access to their application and can add or remove colleagues as required.</td>
</tr>
<tr>
<td><strong>Management of applications</strong></td>
<td>Guest Users can only have one application open within the HREA at a time. All applications must be managed on the Guest Users' computer or device.</td>
<td>Registered Users can have multiple applications in-flight and manage them within the HREA.</td>
</tr>
</tbody>
</table>
2.3 Data storage and access

When the HREA is accessed through a Registered User account all in process applications are automatically stored on the NHMRC server for 365 days from the date created. Applications may also be downloaded to the applicant’s computer at any time and re-uploaded into the HREA to continue working on them.

All submitted applications are stored on the NHMRC server for a period of 30 days. After this time, submitted applications will need to be re-uploaded if a new version needs to be submitted, or a previously submitted version is to be used as the basis for a new application.

Users who access the HREA as a Guest User cannot store any data on the NHMRC server. Applications will need to be downloaded to the local computer in order to save them. It is recommended that Guest Users regularly save their work to their computer.

NHMRC staff cannot view users’ ‘in progress’ or submitted applications. NHMRC only collects data on the HREA’s usage and other generalised metrics on the types of applications being completed.
2.4 HREA layout

The HREA has an introductory declaration, followed by four sections. The declaration explains the basic information researchers must understand before they completed the HREA.

2.4.1 Project Overview

The Project Overview Section contains questions the HREC requires to understand some fundamental aspects of the proposed research. This includes a lay summary, details of where the research will be conducted, details of the project team, any interests they might have and details of any prior evaluations, such as ethics or scientific review.

This section also includes selectable lists of research methods and participant groups. Selecting the methods and participant groups applicable to the research project generates a set of ethical questions and guidance unique to those methods and participant groups.

If none of the methods or participant groups are applicable to the project only a set of generic questions are asked.

2.4.2 Project Details

The Project Details Section contains questions on four key areas – Recruitment, Consent, Risk, and Benefit. In this section applicants will provide details on how participants will be recruited, how consent will be obtained and explain the ethical implications of the approach. Applicants will also explain the risks of the research and how these will be address and detail the benefits of the research. If specific methods or participant groups are selected in the Project Overview Section, the Project Details Section will contain questions and guidance specific to these. In this section it may be necessary to refer to sections of the Project Description/clinical trials protocol and guidance is provided to prompt this to occur.

2.4.3 Data and Privacy

The Data and Privacy Section is applicable to all human research, and focuses on two key areas – the characteristics of the data that will be collected and used in the proposed project and the proposed activities to be carried out with the data. Questions also elicit information on what will happen to the data and results after the project is completed.

2.4.4 Finalise and Submit

The Finalise and Submit Section allows applicants to attach the Project Description/clinical trials protocol, any other relevant documents (such as patient information and content forms, questionnaires and departmental approvals), digitally sign the application, download a copy of the completed form and attachments for their records and, when supported, submit the form electronically to their HREC. Where electronic submission is not supported by the HREC, the HREA will indicate the preferred method of submission (email or hard copy) and provide the email/postal address.

2.4.5 The HREA and the Project Description/Clinical Trials Protocol

An ethics application consists of two main components – a Project Description (or, in the case of clinical trials, a clinical trials protocol) that contains information on the methods and activities that underlie the proposed research and a written reflection of how the proposed research meets the principles and requirements of the National Statement. The former, which will set the context for the proposed project, is often in place before the application for ethics review, for example in the shape of a clinical trials protocol, PhD proposal, grant funding proposal etc. By attaching this document to the HREA and cross-referencing as appropriate repetition can be avoided.
2.5 Saving, previewing, uploading and sharing applications

The HREA makes it simple to save, preview, upload and share your ethics applications.

2.5.1 Saving applications

Registered Users applications are saved every time you move between fields and/or pages. It is also recommended that you save regularly using the ‘save application’ button.

For Guest Users the application will retain information as you move through the form, but this information will be lost if you close the form or web browser without manually saving the application. To save an in progress application guest users will need to save the form to their local computer by clicking the ‘save application’ button. This will prompt the user to download a file with the omni suffix. This .omni file is the unique file format used by the HREA that contains the form data as well as any attachments. This file can only be opened in the HREA and will not open in any other programs. The Guest User can then re-upload this file into the HREA when they want to continue completing their application.

Once applicants complete and submit their applications they are prompted to download and save a .omni file. This file can be uploaded into the HREA to amend the application. As such it is essential that applicants download this file and save it in a safe space.

2.5.2 Previewing applications

Both Registered Users and Guest Users can preview ‘in progress’ applications at any time by clicking the preview button. This will download the application, in its current state, in both .pdf and .rtf formats within a .zip file.

2.5.3 Uploading previously submitted applications

Once applicants complete and submit their applications they are prompted to download and save an .omni file. This file can be uploaded into the HREA to amend an application that was submitted longer than 30 days ago. As such it is essential that applicants download this file and save it in a safe space.

2.5.4 Sharing applications

Registered Users can share applications between one another using the ‘share application’ button on the Application Page. This feature allows users to grant access to a collaborator, supervisor or any other Registered User, who can review and edit the form. This feature can also be used to quickly and easily obtain digital signatures of all investigators on the application. If an application is shared with a collaborator who does not have an account, they will be prompted to register in order to access the application. Guest Users can also share applications by downloading and emailing the .omni file, which can then be uploaded, reviewed, edited by the collaborator before the application is then downloaded and returned to the original user.
2.6 Managing applications

Each application has four data fields that distinguish it from other applications and identify if any other applications are related. These are outlined on the first page of the PFD/Word document and included in the XML data file.

Application ID – This is a unique identifier created for every application in the HREA system. Your applications will start with your initials and be followed by a four digit number (e.g. JC0428, RR1003 etc). The Application ID of your applications will not likely be the next number (e.g. AP0001 then AP0002 etc) but rather skip a few digits (e.g. AP0001 then AP0007 etc).

Version Number – This number identifies the position and order of the application compared to other versions of the application. Every new application will start with a Version Number of “1”. Each time a new version of an application is created, the version number will increase by 1. If an application had a Version Number of “7” this would imply that there were six previous versions of the application.

Parent Application ID – This field is blank unless this application is a new version of a previous application. Where a Parent Application ID is shown it identifies the predecessor application that was used to create this new version (e.g. if a new version of AP0009 was created to make AP0010, the Parent Application ID of AP0010 would be AP0009).

Originating Application ID – This field is blank unless this application is a new version of a previous application. Where an Originating Application ID is shown it identifies the first/earliest application in a series of applications that were used to create this new version (e.g. if a number of new versions of AP0001 were created to ultimately make AP0010, the Originating Application ID of AP0010 would be AP0001). Where there has only been one new version of an application created, the Parent Application ID and Originating Application ID will be the same.
2.7 Copying and making amendments to applications

The HREA allows Registered Users to copy their applications and either create new, unrelated applications or create new versions of existing applications, such as required if amending an application.

2.7.1 New applications

The HREA allows Registered Users to copy their application data to a new application. This is useful when an applicant is planning to undertake multiple research projects that are unrelated but have similar information (e.g. the same research team or use the same recruitment and consent strategy). Each time a new application is made its Version Number is set to “1”.

2.7.2 New versions

The HREA allows Registered Users to create new versions of existing applications. This is useful when an applicant has submitted an application and then wants to submit an amended version for review (i.e. to incorporate changes based on HREC feedback). Each time a new version of an application is made the Version Number increases by one.

2.7.3 Tracked changes version

Researchers may want to revise a submitted application and resubmit it for review. This will commonly only occur were an error was made in the application or the reviewing HREC has provided feedback that requires changes to the application. Registered Users are able to create new versions of their submitted applications. If a new version is created of a submitted application, the HREA provides the Registered User with a track changed PDF that highlights the differences between the versions. This will happen automatically within the HREA and can be accessed when editing the application and when it is submitted.
3 How-to guide

3.1 Account management

3.1.1 Create new account

Navigate to 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. The password box will turn green once the complexity requirements are met.
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.
3.1.2 Sign in with registered account

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

2. Accept licence agreement.
3.1.3 Reset 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. Provide 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. If you have successfully reset your password you will see the below notification.
3.1.4 Manage profile

1. Sign in with a 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’
3.1.5 Change username

1. Sign in with a registered account.

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

3. Select ‘account settings’.
4. Select ‘change username’.

5. Enter password and new username and select ‘save’. Note that the username must be an active email address, as a confirmation/activation email will be sent to this 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 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.

8. Enter the new username and password to confirm the change has occurred.
9. Select the ‘Profile’ button on the HREA front page.

10. Select ‘email details’.

11. Select ‘Add new email address’.

12. Enter the new username, tick ‘preferred’ and select ‘save’.
3.1.6 Change password

1. Sign in with a registered account.

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

4. Select ‘Change password’.

5. Enter current password and 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.
3.1.7 Guest access

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

1. Select ‘Guest Access’.

2. Accept licence agreement.
3.2 Starting a new application

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

2. Select the ‘New application’ button
3.3 Navigating the HREA front page

Top 5 in progress applications

Below are your applications. Click the link to open an existing application, use the ‘New application’ button below to start one, or click the ‘Upload form’ button to resume a downloaded application.

<table>
<thead>
<tr>
<th>Application identifier</th>
<th>Title</th>
<th>Status</th>
<th>Found</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR00237</td>
<td>Upload of test</td>
<td>In Progress</td>
<td>Human Research Ethics Application</td>
</tr>
<tr>
<td>RD0016T</td>
<td>Almost cone 2</td>
<td>In Progress</td>
<td>Human Research Ethics Application</td>
</tr>
<tr>
<td>RD0016G</td>
<td>Almost cone 3 (edited to have...</td>
<td>In Progress</td>
<td>Human Research Ethics Application</td>
</tr>
<tr>
<td>RD00221</td>
<td>Test app for incomplete submit.</td>
<td>In Progress</td>
<td>Human Research Ethics Application</td>
</tr>
<tr>
<td>Number</td>
<td>Name</td>
<td>Function</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Home</td>
<td>Return to the HREA landing page</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Session timer*</td>
<td>Count-down session timer.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>General information</td>
<td>Access general information pages</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Application page*</td>
<td>Access application page</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>User profile page*</td>
<td>Access user profile page</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Page-specific help</td>
<td>Access page-specific help</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Log out</td>
<td>Log out of the HREA</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Start new application</td>
<td>Start a new application</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Upload existing application</td>
<td>Upload an existing application into the HREA using the .omni file previously downloaded to your computer.</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>List of most recent applications*</td>
<td>Quick access to the five most recent ‘in progress’ applications</td>
<td></td>
</tr>
</tbody>
</table>

*Registered users only.

^This security feature protects user accounts and information. When the timer runs out the user will be logged out of the HREA. Once the timer is less than 30 minutes, it can be restored by navigating between the Information, Applications or Profile tabs. You will receive a warning when there is one minute remaining.

### 3.3.1 Information

This page contains information and guidance on aspects of the HREA, human ethics and other relevant topics. These pages will be updated with content as it is developed.

To access the individual content pages, click on the page on the left of the screen.
3.3.2 Applications (Registered users only)

This page allows the user to view and manage their ‘in progress’ and submitted applications.

Note that the submitted applications will only be stored temporarily (for 30 days post submission), and users should ensure they download a copy for their records upon submission to the HREC.

Note that ‘in progress’ applications will only be stored for 356 days. Users should download a copy of their application as a omni file before this date.
### 3.3.3 Navigating the Applications page

![Image of the NHMRC Applications page]

#### Applications

This page shows all applications you can access.

Below are your applications. Click the link to open an existing application, use the ‘New application’ button below to start a new one, or click the ‘Upload application’ button to resume a downloaded application.

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Title</th>
<th>Status</th>
<th>Owner</th>
<th>Round</th>
<th>Stage</th>
<th>Status</th>
<th>Created date</th>
<th>Modified date</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR00420</td>
<td>complete test - Copy of RR00420</td>
<td>Submitted</td>
<td>Rob Rigby</td>
<td>Human Research Ethics Application</td>
<td>10</td>
<td>Open</td>
<td>24/02/2016 03:21 AM</td>
<td>24/02/2016 11:45 AM</td>
</tr>
<tr>
<td>RR00674</td>
<td>Test app #2</td>
<td>In Progress</td>
<td>Joel Ceramidas</td>
<td>Human Research Ethics Application</td>
<td>1</td>
<td>Open</td>
<td>11/02/2015 00:49:34 PM</td>
<td>11/02/2015 00:49:34 PM</td>
</tr>
<tr>
<td>RR00339</td>
<td>test</td>
<td>In Progress</td>
<td>Rob Rigby</td>
<td>Human Research Ethics Application</td>
<td>1</td>
<td>Open</td>
<td>04/02/2016 06:34:54 PM</td>
<td>04/02/2016 06:34:54 PM</td>
</tr>
<tr>
<td>RR00168</td>
<td>Almost done 3 (needed to have more full answers)</td>
<td>In Progress</td>
<td>Rob Rigby</td>
<td>Human Research Ethics Application</td>
<td>1</td>
<td>Open</td>
<td>11/11/2015 04:12:01 PM</td>
<td>11/11/2015 04:12:01 PM</td>
</tr>
</tbody>
</table>

Showing 1 to 7 of 7 entries
<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Start new application</td>
<td>Start a new application</td>
</tr>
<tr>
<td>2</td>
<td>Upload existing application</td>
<td>Upload an existing application into the HREA using the .omni file previously downloaded to your computer.</td>
</tr>
<tr>
<td>3</td>
<td>Search</td>
<td>Search the list of applications</td>
</tr>
<tr>
<td>4</td>
<td>Expand application management buttons</td>
<td>See below for details</td>
</tr>
<tr>
<td>5</td>
<td>Application identifier</td>
<td>Indicates unique identifier</td>
</tr>
<tr>
<td>6</td>
<td>Title</td>
<td>Indicates application HREA title. This may be different to the formal project title given for the application within the HREA form.</td>
</tr>
<tr>
<td>7</td>
<td>Status</td>
<td>Indicates application status</td>
</tr>
<tr>
<td>8</td>
<td>Owner</td>
<td>Indicates application owner</td>
</tr>
<tr>
<td>9</td>
<td>Round</td>
<td>Indicates the form used. Currently there is only one form, the HREA.</td>
</tr>
<tr>
<td>10</td>
<td>Stage</td>
<td>For the HREA this will always indicate '1'.</td>
</tr>
<tr>
<td>11</td>
<td>Status</td>
<td>Used to indicate the status of any time-limited forms. The HREA will always be 'open'. This is independent of any submission time constraints an individual HREC might impose.</td>
</tr>
<tr>
<td>12</td>
<td>Created date</td>
<td>The date and time an individual application was created.</td>
</tr>
<tr>
<td>13</td>
<td>Modified date</td>
<td>The date and time an individual application was last modified.</td>
</tr>
<tr>
<td>14</td>
<td>Share icon</td>
<td>Indicates that the application is shared with other users.</td>
</tr>
<tr>
<td>15</td>
<td>Navigate</td>
<td>Navigates between pages of applications.</td>
</tr>
</tbody>
</table>

Some of the application table information may be condensed if it can’t fit on one row in your browser. In this case, click on the icon to expand the condensed list and view the information.

**3.3.4 Application management buttons**

To view the application management buttons, select the icon.
<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Expand Table" /></td>
<td>Expand table</td>
</tr>
<tr>
<td><img src="image" alt="Expand App Management" /></td>
<td>Expand application management buttons</td>
</tr>
<tr>
<td><img src="image" alt="Copy" /></td>
<td>Copy application</td>
</tr>
<tr>
<td><img src="image" alt="Download" /></td>
<td>Download application as a .omni file to the device/computer</td>
</tr>
<tr>
<td><img src="image" alt="Share" /></td>
<td>Share application with other HREA registered user/s</td>
</tr>
<tr>
<td><img src="image" alt="Rename" /></td>
<td>Rename application</td>
</tr>
<tr>
<td><img src="image" alt="Delete" /></td>
<td>Delete application</td>
</tr>
<tr>
<td><img src="image" alt="View Attachments" /></td>
<td>View application attachments (submitted application only)</td>
</tr>
<tr>
<td><img src="image" alt="Compare Versions" /></td>
<td>Compare versions (new versions of a submitted application only)</td>
</tr>
</tbody>
</table>

### 3.3.5 Profile (Registered users only)

This page allows Registered Users to add and edit their personal details, address, phone number, email and account settings (i.e. change their username and password). To access the above pages select the page on the left hand side of the screen.
3.3.6 Help

This page provides screen-specific help and guidance. Not all pages will have specific guidance, and guidance will be developed and added over the life of the HREA in response to user feedback.
3.4 Navigating the HREA

The following outlines the key features of an example HREA page. The numbers correspond to the table below.
3.4.1 Navigation pane

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Function/notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Completed page</td>
<td>Green text highlights pages that have been visited and are complete (i.e. there are no more compulsory fields to answer)</td>
</tr>
<tr>
<td>2</td>
<td>Incomplete page</td>
<td>Orange text highlights pages that have been visited but are not yet complete (i.e. one or more compulsory fields outstanding)</td>
</tr>
<tr>
<td>3</td>
<td>Current page</td>
<td>Bold text indicates current page in navigation pane</td>
</tr>
<tr>
<td>4</td>
<td>Un-viewed pages</td>
<td>Grey text indicates un-viewed pages in navigation pane.</td>
</tr>
</tbody>
</table>

Users can click on any of the pages in the Navigation pane to skip to that section. The HREA does not necessarily need to be completed in order.
### 3.4.2 Navigation tools

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Function/notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Preview application</td>
<td>Download a preview of the application in the format it will be submitted to the HREC (i.e. PDF/Word document).</td>
</tr>
<tr>
<td>6</td>
<td>Save application</td>
<td>For Registered users, save application to NHMRC server.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For Guest Users, save the application to their computer</td>
</tr>
<tr>
<td>7</td>
<td>Navigate forwards</td>
<td>Move to next section of the HREA that contains unanswered fields. If there are unanswered fields on the current page, the button will not go to the next page.</td>
</tr>
<tr>
<td>8</td>
<td>Navigate backwards</td>
<td>Move to previous section of the HREA</td>
</tr>
</tbody>
</table>
3.4.3  Form page

Project Team

Provide information on the investigators/researchers conducting the research project.

- National Statement 1.1 (e) states that:
  
  “Research that has merit is...conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research”.

- In establishing the research team you should ensure there is appropriate and sufficient expertise to undertake all the research activities.
- Ensure that you detail who is undertaking the research activities and their expertise, qualifications and competence.

Team Member Details

Prof John Citizen

<table>
<thead>
<tr>
<th>Title</th>
<th>Optional</th>
<th>First Name</th>
<th>Surname/family name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof</td>
<td></td>
<td>John</td>
<td>Citizen</td>
</tr>
</tbody>
</table>

Email Address *
- Provide the preferred contact email address.

john.citizen@nhmrc.gov.au

Institutional affiliation and position *
- Identify the person’s institution and position as relevant to the research.
- Institutional requirements for this information may differ.
- If the person has positions at multiple institutions, all of those relevant to the research should be listed.

Professor at City University

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Function/notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Expand/contract</td>
<td>Expand or contract current section. Only available for certain sections of HREA.</td>
</tr>
<tr>
<td>10</td>
<td>Compulsory field</td>
<td>Compulsory fields are marked with an orange asterisk. They can be skipped, however the HREA will not be able to be submitted with outstanding compulsory fields.</td>
</tr>
<tr>
<td>11</td>
<td>Rich text entry</td>
<td>Some fields allow rich text entry, allowing bold, italic, dot points, symbols etc. A small number of fields also allow the insertion of tables when appropriate to the question being asked.</td>
</tr>
</tbody>
</table>
Q1.9.1.2 Attach evidence of the outcome of the scientific or academic review process.
- Evidence may include an outcome letter or other formal correspondence received from the persons providing the review.
- Attachments are limited to 2MB in size.

12 Upload attachment
Allows attachments to be uploaded at specific points throughout the form.

Q1.9.2 Has this research project had prior ethics review?
- If the project has been previously reviewed it may not require review again.
- Contact your institution’s research office for guidance on whether your project requires ethics review.

13 Yes/No button
The selected answer is shown in dark blue (e.g. for the above, 'Yes' is selected).

Provide the following details for each ethics committee that has previously reviewed the application.

Q1.9.2.1 Which ethics committee previously reviewed the application?
- Provide the full, formal title of the ethics committee or reviewing body.

Note that under the TGA Act 1989 an ethics committee must be registered with the NHMRC in order to approve clinical trials undertaken as part of the Clinical Trials Notification (CTN) scheme.

Q1.9.2.2 What was the outcome of the ethics committee review?
- If the research was approved with conditions or requirements outline what these are and how they will be met.

Number | Name | Function/notes
--- | --- | ---
12 | Upload attachment | Allows attachments to be uploaded at specific points throughout the form.
13 | Yes/No button | The selected answer is shown in dark blue (e.g. for the above, 'Yes' is selected).
14 | Select row | Select a row added to a table for deletion.
15 | Add/delete row | Select plus symbol to add a row, or select minus symbol to delete a selected row.
3.5 Entering information into the HREA

The HREA can be completed in any order. Information is entered in a number of ways. Where there is a limit on the word count for a certain field this is indicated. The following table outlines the various ways information is added into the HREA.

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit your title to 60 words or fewer.</td>
<td>Plain text</td>
<td>User can only enter plain text</td>
</tr>
<tr>
<td>[Image]</td>
<td>Rich text</td>
<td>User can use 'rich text' functions, such as bold, italics, underline, symbols, bullet points and spell checking</td>
</tr>
<tr>
<td>[Image]</td>
<td>Yes/No</td>
<td>The selected answer is indicated by the dark blue, the non-selected answer by light blue.</td>
</tr>
<tr>
<td>[Image]</td>
<td>Pull-down list</td>
<td>User can select one option only from a list</td>
</tr>
<tr>
<td>[Image]</td>
<td>Table (add/delete row)</td>
<td>User can add and delete rows from a table</td>
</tr>
<tr>
<td>[Image]</td>
<td>Multiple options list</td>
<td>User can select multiple options from a list</td>
</tr>
</tbody>
</table>
3.6 Attaching documents to the HREA

Supporting documents can be attached to the HREA. The inclusion of a project description/clinical trials protocol is mandatory. Other supporting documents will depend on the type of research being proposed and institutional/HREC requirements, but may include participant information and consent forms, questionnaires, report forms and advertising materials. In some cases the HREA may request documents to be added as you complete the questions, rather than at the ‘Uploads’ page. This is carried out using the same procedure detailed below.

3.6.1 Attaching the Project Description/Protocol

As a Project Description/Protocol is mandatory, this is attached separately to any other relevant documents.

1. Navigate to the Upload page

2. 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 document has been uploaded. Selecting ‘Open’ will download the attached document. The attached document is a copy of the original document, which will remain on your computer.
6. To remove the attached Project Description/Protocol, select ‘Clear content selection’.

3.6.2 Attaching 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 on the button to add rows to the attachments table. One row will be needed for each attachment.
In this example, three rows have been added.

3. To add attachment, select ‘upload new’
4. Select ‘Choose file’ – the HREA will open the file explorer on your computer

5. Select file for attachment and select ‘open’.
6. Ensure correct filename is listed and select ‘Start upload’

7. Confirm document has been uploaded. Selecting ‘Open’ will download the attached document. The attached document is a copy of the original document, which 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 delete button. The attachment will be removed from the HREA, but the original will remain on your computer.
3.7 Declarations

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 or by signing on screen.

3.7.1 Attaching a digital signature

1. Navigate to ‘Declarations’ page and select ‘Upload signature’.

2. Select ‘Upload New’ and select ‘Open’.
3. Ensure correct filename is listed and select ‘Start upload’

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

5. To remove the attached signature document, select ‘Clear content selection’.
3.7.2 Signing 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.
3.8 Submitting your HREA for review and downloading your application for your records.

The method by which your application will be determined by the Human Research Ethics Application (HREC).

1. Navigate to the HREC page.
2. Use the pull down list to select the organisation that hosts the HREC (or other review body) you wish to submit your application to.

3. Selecting an Organisation will generate a list of HRECs (or other review bodies) hosted by the Organisation. Select the HREC (or other review body) to which you wish you want to submit your application.
4. Contact information for the selected HREC or review body will be displayed.

5. Navigate to the Download and Submit page.

6. Verify that the application is complete, the Project Description/Clinical Trials Protocol has been attached and that it is ready to be submitted. Select ‘Download and Submit’.
7. If the form is incomplete you will not be able to submit until all mandatory sections have been completed. Incomplete sections are marked in orange.

8. Once the form is complete, select the ‘Download and Submit’ button.
9. The ‘Download files’ dialogue box will open.

10. Download the files you require 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 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.

It is strongly recommended that you download both the .omni file and the .zip file and keep them in a safe place.

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 all of the available files that I require’ and select ‘Next’.

12. You will be notified as to how your chosen HREC wishes to receive the application. Follow the instructions provided to submit your application. In the example below, the HREC only accepts hard copy applications. 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 next example, the HREC only accepts applications via email. Clicking on the email address will open your email program and automatically address the email to the correct address. You will need to attach the .zip file downloaded in the previous step and complete the email subject and body text as desired.

14. 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.
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.
3.9 Revising and resubmitting a previously submitted application

HRECs or other 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.

For registered users, submitted applications are stored in the HREA for 30 days. If longer than 30 days has past, the previously submitted application .omni file will have to be uploaded.

**If you need to upload a .omni file:**

1. Select ‘Upload application’.

2. Navigate to the .omni file for the application you wish to upload and click ‘open’
If your previously submitted file is still listed in the HREA applications list:

1. Navigate to the Applications page and expand the menu next to the submitted application you want to revise.

2. Select the 'Copy application' button.
Once you have imported a previously submitted file or copied a previously submitted file:

1. Once you have either imported your .omni file or selected ‘copy application’ you will see the following dialogue box that will ask you if you want to create a new application or a new version.

2. Select ‘New version’.
3. Enter the title of the new version and select ‘New version’.

4. The new version will be added to your Applications list.
5. The new version can be opened, reviewed and edited. Note that, when a new version of an existing form (whether that existing form has been submitted or not) a copy with changes highlighted can be downloaded.

Selecting the button will generate a pdf 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.

6. The submit/new version/amend/submit process can occur as many times as necessary.
3.10 Using a previously submitted 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. For example, if you regularly make applications with the same investigator team you can create a template that contains all their information, avoiding the need to enter it every time you create an application.

1. Import a previously submitted file or copy a previously submitted file following the instructions above.

2. Select ‘New Application’.

3. Enter the title of the new application and select ‘New application’.
4. The new application will be added to your Applications list.

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

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 locally as .omni files, as inactive applications will be removed from the HREA after a period of time.
3.11 Viewing 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 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 in order 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.

4. The PDF document clearly shows the changes made to the submitted application.
3.12 Submitting 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 detailed under ‘Submitting your HREA to a Human Research Ethics Committee (or other review body) and downloading 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.

It is strongly recommended that you download the .omni file the .zip file the tracked changes .pdf file and keep them in a safe place.

Ensure you have all the files you need before moving from this page.
3.13 Viewing version details in an output document

Every HREA PDF and Word document will have the application management information on the top of the page. This will include the Application ID, Version Number, Originating ID and Parent ID. See “2.6 Managing applications” section for more information about these terms.