



Australian Government
National Health and Medical Research Council

Update on the release of the Human Research Ethics Application (HREA)

Introduction

This is the first newsletter on the HREA since its release in December 2016. It provides an update on the usage of the HREA, solutions to the most common issues experienced by users and an update on activities NHMRC is undertaking to roll-out the HREA.

HREA usage

At the time of publishing this update:

- There are more than 2100 registered users of the HREA,
- More than 820 applications have been created since the release of the HREA, of which over 220 have been submitted, and
- There are at least 67 Human Research Ethics Committees (HRECs) who accept the HREA¹.

Progress Update

Since the release of the HREA, NHMRC has:

- Developed additional training and educational materials which are available at: <https://www.nhmrc.gov.au/health-ethics/human-research-ethics-application-hrea/hrea-support>,
- Continued working with information management system vendors to ensure the compatibility of the HREA with other systems and to facilitate its integration into these systems², and
- Monitored the performance of the HREA system and implemented updates to improve user experience: for example, implementing the new HREA homepage. This has necessitated a small number of brief 'outages'.

¹ At this time, jurisdictions that are party to the National Mutual Acceptance (NMA) Scheme have indicated that HRECs within their public hospital system will not accept the HREA until around mid-2017. Researchers at public hospitals participating in the NMA Scheme are advised to review the guidance provided in the November 2016 HREA Update newsletter:

https://www.nhmrc.gov.au/files/nhmrc/file/health_ethics/human/hrea_updatenov_2016_final_0.pdf

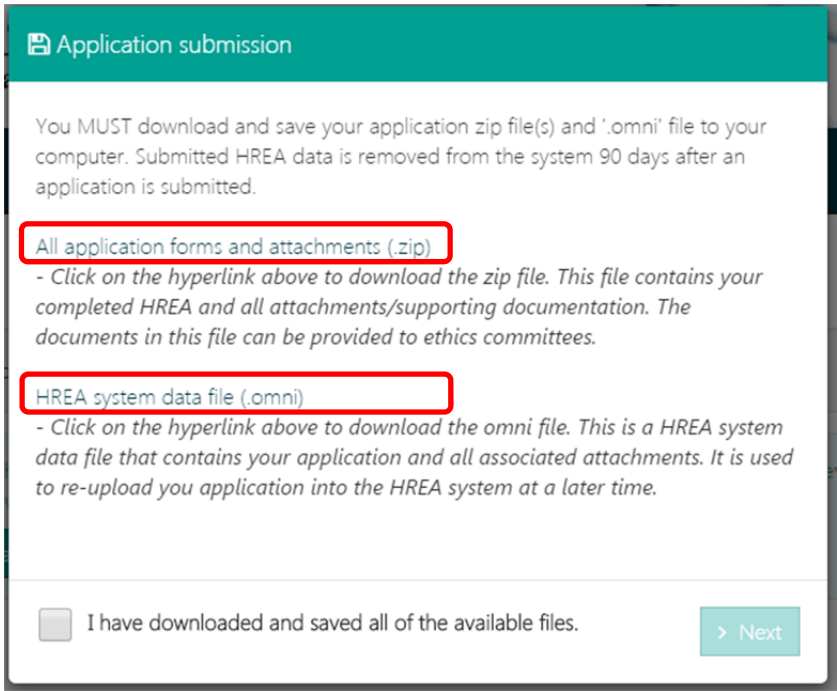
² To date NHMRC has licenced the HREA content to two providers and are progressing licenses with a number of others.

Common user issues and solutions

As a mechanism to educate users and system owners, we have included a number of the most common issues on which users seek advice.

In the first instance, however, users who experience an issue with the HREA are encouraged to first consult the User Guides available on the NHMRC website at: <https://www.nhmrc.gov.au/health-ethics/human-research-ethics-application-hrea/hrea-support>. If this does not resolve the issue, researchers should contact their ethics/research office and then, if necessary, escalate the issue with HREA Help on help@hrea.gov.au or 02 6217 9902.

Solutions to the most common issues reported to HREA Help are outlined below.

Issue	Recommended Solution
How do I obtain a copy of my completed HREA?	<p>Immediately after you have finished your application and pressed the 'Generate HREA document' button a pop-up window will appear that contains options for you to download your application. Click on the 'All application forms and attachments (.zip)' AND 'HREA system data file (.omni)' hyperlinks to download your application.</p>  <p>If you have closed this window you can obtain your application by following the instruction provided in the 'How to download and save your completed HREA ' user guide available at: https://www.nhmrc.gov.au/files_nhmrc/file/research/clinical_trials/how_to_download_and_save_your_completed_hrea.pdf</p>
The zip file containing my application won't open on a Mac. What do I do?	<p>Follow the instructions provided here: https://www.nhmrc.gov.au/files_nhmrc/file/health_ethics/human/hrea_troubleshooting_-_opening_a_zip_on_a_mac.pdf</p>
I have downloaded the 'omni' file. What is this and why won't it open on my computer?	<p>The 'omni' file is a unique file type to the HREA which you cannot open on your computer. You can only open it by loading it into the HREA system.</p> <p>This file is a data file that contains your HREA and any attachments you uploaded with your application. The file can be re-uploaded into the HREA system if you need to make amendments to your application or if you want to use the application as a template to create a copy of the application in the future.</p>

	Follow the instructions at Section 2.3.2 of the 'How to' User Guide to re-upload your omni file into the HREA. See here: https://www.nhmrc.gov.au/files/nhmrc/file/health_ethics/human/hrea_how_to_guide.pdf
Can I use my NEAF account on the HREA? Will my NEAF applications appear in the HREA?	No. The NEAF and HREA are built using different IT software so you will need to create a new account to use the HREA. Applications created in the NEAF will not appear in the HREA. Where necessary, NEAF applications can be manually reproduced in the HREA by copying and pasting text between the two forms.

Withdrawal of support for the NEAF

Now that the HREA has been launched and the number of users is increasing, NHMRC will work toward ceasing support for the NEAF, including decommissioning the NEAF website on 30 June 2017. It is recommended that any new ethics applications are created on the HREA. However, researchers should confirm with their ethics/research office as to whether the institution will accept the HREA before commencing the application. A version of NEAF will continue to be hosted in the short term on the website <https://au.ethicsform.org/>.

Further information

If you would like more information on the HREA, please contact us at clinicaltrials@nhmrc.gov.au or call Dr Gordon McGurk, Director, Clinical Trials Section on 02 6217 9320.