Streamline E-bulletin

Streamlining multi-centre research | August 2017

What is the HREA?

The Human Research Ethics Application (HREA) form is a new ethics application form developed by the National Health and Medical Research Council (NHMRC). The HREA replaces the National Ethics Application Form (NEAF).

Where can I use the HREA?

The HREA will be located on Online Forms and used for an application to an ethics committee at a public health organisation (hospital). The HREA can be used for any ethics application in a jurisdiction that participates in National Mutual Acceptance (NMA).

When can I use the HREA?

From 31 August 2017* you can create a HREA in Online Forms. From 31 August 2017* you can no longer create a new NEAF.

Just log on to Online Forms and use the application form that available. The link to Online Forms can be found via the Melbourne Health website: https://www.thermh.org.au/research/researchers

***Launch date is dependent on NHMRC issuing a final notification of the HREA licence to Infonetica, the provider of Online Forms**.

What about existing NEAFs?

Don't panic! Existing NEAFs are not affected.

If you created a NEAF before 31 August 2017, you can complete the form, upload supporting documents, electronically authorise and submit the application. You can still create site specific assessment (SSA) forms too.

If you have recently submitted a NEAF that is undergoing ethical review, you can use Online Forms to respond to information requests from the reviewing ethics committee and to create SSAs.

Legacy information (all old NEAFs) remain in the Online Forms system. You can use an existing NEAF to create SSAs or to submit post-approval information.

For what types of research can I use the HREA?

You can use the HREA for:

- clinical trial
- any type of health/medical research
- single-site project
- multi-site project
- project within one state/territory
- project under NMA

How do I use the HREA?

When you log in to Online Forms after 31 August 2017, select 'Create New Project' and then 'HREA'. The Online Forms HREA is used in exactly the same way as the NEAF – complete the form, upload supporting documents, create SSAs, electronically authorise and submit to the reviewing organisation.

Do I have to complete the Victorian Specific Module?

Yes. When the HREA is used and the research project involves a site in Victoria, the Victorian Specific Module (VSM) must be uploaded as a supporting document to the HREA and submitted to the reviewing ethics committee (even if the committee is outside Victoria).

Can I still use the LNR VIC form?

Not at Melbourne Health. The Melbourne Health Office for Research, in consultation with other institutions hosting Victorian NHMRC/ NMA certified reviewing HRECs, has decided to use one ethics application form only – the HREA. The Victorian Low and Negligible Risk application form (LNR VIC) will not be accepted and therefore cannot be used from 31 August 2017. Please note, the LNR VIC is not accepted in other States.

All research projects must be submitted using the HREA, regardless of the level of risk. The HREA is an interactive form that caters for research at all levels. Researchers will only see the questions relevant to the research project they put forward.

Are there any changes to the research governance/SSA process?

No. The process for research governance/site specific assessment (SSA) remains the same.

- On the Online Forms HREA the Coordinating Principal Investigator (or delegate) creates all SSAs for the project
- All supporting documents uploaded to the HREA are automatically available on every SSA
- Each SSA is transferred to the site Principal Investigator (PI) (or delegate)
- The site PI completes their SSA and submits to the site research governance officer

Previously, some SSA questions were automatically populated from the NEAF. A few of these SSA questions are no longer pre-populated as the source questions are not on the HREA, so they will need to be answered on the SSA. Other than that, the SSA process is still the same!

What about SSAs linked to an existing NEAF?

Every SSA has an unbreakable link to the ethics application form from which it was created. SSAs that were created from a NEAF stay linked to that form. From an existing NEAF, SSAs can be created, completed, supporting documents uploaded, electronic authorisation applied, and the SSA can be submitted.

I'm going to start an ethics application soon. Should I wait for 31 August 2017?

It's up to you. If it will not impact your project timelines, it could be a good idea to wait. The HREA will be a more 'future-proof' form, so for submitting amendments or progress reports in coming years, the HREA may be a better choice now. However, if you want to get started on a NEAF now, you can still do so.

Can I convert a NEAF into a HREA?

No. The NEAF, HREA and LNR VIC are separate ethics application forms; you cannot convert one form into another.

Can I get Online Forms training?

Yes. The Coordinating Office offers Online Forms information sessions. Email us to book.

- If you have a group interested in a session, we can come to your site (Victoria only).
- An individual session can be arranged at the Department of Health and Human Services (DHHS) in Melbourne CBD.
- Sessions for sponsors and contract research organisations may be held remotely.

The Victorian Online Forms Handbook is still a useful resource – all information that related to the NEAF now applies to the HREA!

I created a HREA on the NHMRC website – what can I do?

The Online Forms website must be used to complete and submit a HREA in Victoria. If you have used another website to create a HREA, contact the Online Forms Helpdesk for assistance (contact details are in the 'Help' section below).

I'm not sure how to answer some of the HREA questions – who can I ask?

Your organisation's research office can assist you with the content of your ethics application.

The Online Forms HREA is a licenced copy of the HREA developed by NHMRC. Contact NHMRC if you have specific queries or feedback about the questions and information in the form (02 6217 9902, ethics@nhmrc.gov.au).

Western Australia is joining NMA!

Commencing on 31 August 2017*, National Mutual Acceptance (NMA) of ethical review will occur across Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia.

Ethics application

The Human Research Ethics Application (HREA) will be used for all NMA applications from 31 August 2017*.

For detailed information on the ethics application process in each state/territory, consult the relevant jurisdiction's website (details below).

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Jurisdiction-specific information

When applicable, these must be uploaded as supporting documents to the ethics application and submitted to the reviewing ethics committee (irrespective of the committee's location).

- *NSW Privacy Form* if project has NSW site(s) and participants include 'adult persons who are unable to give consent'
- *Victorian Specific Module* (VSM) if project has VIC site(s)
- *Western Australian Specific Module* (WASM) if project has WA site(s)

Research governance for sites in WA

Consult the WA Research Governance Service (RGS) website for information.

Research governance for sites in ACT, NSW, QLD, SA or VIC

The Coordinating Principal Investigator (CPI) must use the Online Forms website to create a Site Specific Assessment (SSA) form for each participating site in ACT, NSW, QLD, SA or VIC.

If the ethical review is performed in WA, the CPI (WA) should use Online Forms to create a Minimal Dataset Form (MDF), upload copy of HREA and supporting documents, create SSA(s) and transfer each SSA to the site Principal Investigator. Instructions will be available on jurisdiction websites (details below) in the near future.

If the ethical review is performed in ACT, NSW, QLD, SA or VIC, the Online Forms process for creating SSAs remains unchanged.

Prior applications

NMA is not retrospective – projects already approved must remain under the arrangements that were in place at the time of their approval. An existing approved state/territory or NMA research project cannot be expanded to include a WA site. An existing WA ethical approval cannot be expanded to include a site in another jurisdiction.

NMA documents

The suite of NMA reference documents has been updated and will be available soon on each jurisdiction's website. Ensure you use the August 2017 versions.

Jurisdiction websites

Australian Capital Territory	www.health.act.gov.au/datapublications/research/human-research-ethics-committee

NEW research agreement for medical technology

The Southern Eastern Borders States (SEBS) panel has negotiated an updated Clinical Investigation Research Agreement (CIRA) with the Medical Technology Association of Australia (MTAA). This dedicated clinical investigation agreement for commercially sponsored studies of medical technology is available on the MTAA website.

Check out the CIRA >>

Clinical trials report

The Clinical Trials Jurisdictional Working Group (CTJWG) has released the *Second Activity Report on Clinical Trials in Australian Public Health Institutions 2015-16*. The report captures data relating to the majority of new clinical trials approved in public health organisations in five jurisdictions in Australia.

View the report >>

News from the Coordinating Office

We are very pleased to welcome Catherine Farrington to our team! Catherine has worked for many years as a clinical trial coordinator and brings plenty of experience and enthusiasm to her new Project Officer role.

Online Forms information sessions

The Coordinating Office offers information sessions on getting the most out of Online Forms.

- If you have a group interested in a session, we can come to your site (Victoria only).
- An individual session can be arranged at the Department of Health and Human Services (DHHS) in Melbourne CBD.
- Sessions for sponsors and contract research organisations may be held remotely.

Arrange an information session >>

Contact us

The Coordinating Office for Clinical Trial Research welcomes your feedback.
General Enquiries: 03 9096 7394

Email the Coordinating Office >>