




NSW HREA FAQs


HREA Overview

When should I start using the HREA?

From 31 August 2017, the Human Research Ethics Application (HREA) replaces the National Ethics Application Form (NEAF) in [Online Forms](#) . All new ethics applications to NSW Human Research Ethics Committees (HRECs) regardless of study risk level should be generated on a HREA inside of [Online Forms](#) . This also applies to all new ethics applications submitted under the [National Mutual Acceptance \(NMA\) scheme](#).


What is the HREA?

The National Health and Medical Research Council's (NHMRC's) [HREA](#)  is an online ethics application form developed for all research involving humans. The HREA is designed to guide applicants through the ethical principles of the National Statement on Ethical Conduct in Human Research (2007).

According to the NHMRC's first [HREA newsletter](#),  "NHMRC, with the oversight and guidance of the HREA working group [developed] the HREA with the aim that the form is applicable to all human research, including low-risk projects to complex multi-centre clinical trials. The HREA aims to streamline and simplify the ethics review application process by only asking the questions that apply to the research in question." A history of the development of the HREA is available in that newsletter.

More information on the HREA, including its development, is available on the [NHMRC website](#) .

Where should I use the HREA?


As of 31 August 2017, the HREA will be located in [Online Forms](#) , the current public health organisation research ethics and governance application website that is used by NSW and some other NMA jurisdictions.

Please do not create a HREA for a NSW public health HREC at HREA.gov.au, NHMRC's HREA-generating website, because the ethics committee will not be able to import and review the application.

What is the difference between the Online Forms HREA and the NHMRC HREA?


Essentially the two forms are the same. NSW Health uses a licensed copy of the NHMRC HREA. The questions on the NSW Health HREA are identical to those on the NHMRC HREA. The only difference between the two forms is that the NSW Health HREA allows data to be imported into the Australian Research Ethics Database (AU RED), which is an online research application tracking and management system used by research offices in the NSW public health system.

How do I use the HREA?

For researchers: 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 the application to the reviewing organisation. The Online Forms User Manual, which provides guidance on how to complete application forms and supporting documents required for making an application, will be updated to reflect the HREA. Under the Help menu, select User Manual.

For research offices: There is no change in the way research offices import and review HREAs in AU RED.

What are the HREA questions?

There is no published list of HREA questions. After 31st of August 2017, the best way to get to know the HREA is to log into to [Online Forms](#) , create a new "dummy" HREA, and to activate different questions to see what subsequent questions result. NHMRC has provided question-specific guidance for many of the questions, which will be visible immediately under the question.

Before 31st of August 2017, you can create a "dummy" HREA application on [NHMRC's HREA website](#). However, please do not create a HREA for a NSW public health HREC at [HREA.gov.au](#), because the NSW Health ethics committee will not be able to import and review the application.

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.

What if I accidentally created a HREA at [HREA.gov.au](#)?

The Online Forms website must be used to complete and submit a HREA to NSW Health HRECs. 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).

Importing the external HREA into Online Forms might be possible in limited circumstances; you may contact the Office for Health and Medical [Research Ethics and Governance Unit](#) for more information.

Key Changes

What are the key changes research offices, HRECS and researchers need to be aware of to prepare for the HREA?

For researchers: *Online Forms functions application processes have not changed.*

Researchers still complete their applications the same way as always inside of Online Forms. All Online Forms functions that you use, such as application signatures, transfers and document uploading remain the same. A minimal amount of information from the HREA will populate into the SSA forms, as before.

Only the ethics and the LNR SSA application forms themselves have changed. Researchers will now complete all ethics applications regardless of risk level on a HREA. Similarly, all SSA applications will be completed on a NSW SSA application regardless of risk level. See the FAQ immediately below for additional information.

For research offices: *AU RED functions have not changed.* You can still register, import, and process ethics and SSA applications inside of AU RED the same way as always.

Only the ethics and the LNR SSA application forms themselves have changed, as outlined above (“for researchers.”)

Overview of application form changes as of 31 August 2017

Forms:	Before:	As of 31 August 2017:
Ethics application	NEAF	HREA
SSA application	NSW SSA	NSW SSA
LNR application	NEAF LNR	HREA
LNR SSA application	LNR SSA	NSW SSA

What about applications for low and negligible risk (LNR) studies?

Ethics applications: The process for submitting an ethics application for LNR review will not change. However, as of 31 August 2017, all applications will be submitted on a HREA form regardless of risk level, because the HREA has been designed as a smart form to accommodate all risk levels: you only need to answer questions which relate to the type of research you are proposing.

HREA question 4.5 will ask under which review pathway you are intending to submit the application (greater than low risk, low risk, negligible risk).

When an investigator intends to submit an application as a LNR project for expedited HREC review, the HREC Executive Officer has the discretion to request that the research project be reviewed under full HREC review. This has not changed.

SSA applications: The process for submitting an SSA application for LNR review will not change. However, as of 31 August 2017, all applications will be submitted on a NSW “full” SSA form regardless of project risk level.

Thematically, the NSW LNR SSA form covered all of the same information as the NSW SSA form. This change will facilitate further consistency in SSA applications in the lead-up to the REGIS launch.

How will the HREA affect the SSA?

The process for research governance/SSA remains the same after the launch of the 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); and, the site PI completes the SSA and submits to the site RGO.

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.

What if I've already started my application on a NEAF, an LNR, and/or a NSW LNR SSA form?

In-progress NEAF and LNR forms: If you created a NEAF or LNR application before 31 August 2017 in Online Forms, you will still be able to complete the form, upload supporting documents, electronically authorise and submit the application. You can still create SSA forms attached to those applications.

Legacy information (old NEAFs, LNRs and LNR SSAs) will remain in the Online Forms system. Any NEAF or NSW LNR form that was already in the [Online Forms](#)  system remains saved in Online Forms, and can still be completed, submitted and processed. You can still create SSA forms related to those applications as well.

In-progress LNR SSA forms: NSW LNR SSA applications that are already in progress as of 31 August 2017 will not be affected. Any LNR SSA form that was already in the Online Forms system remains saved in Online Forms, and can still be completed, submitted and processed.

National Mutual Acceptance (NMA) applications under HREA

What applications should I use to apply for HREC review under National Mutual Acceptance (NMA)?

All NMA HRECs that use Online Forms will be transitioning from the NEAF to the HREA at the same time, on 31 August 2017. In other words, all NMA jurisdictions (ACT, NSW, QLD, SA, VIC) will start using and accepting the HREA at that time.

Please see National Mutual Acceptance for more information about applications submitted under that scheme (e.g. for multi-centre, multi-jurisdictional projects).

If you are submitting an ethics applications to an HREC that is located in a jurisdiction that is not currently part of NMA (Northern Territory, Tasmania), please contact that HREC to obtain its local submission requirements.

What are other National Mutual Acceptance (NMA) jurisdictions doing about low and negligible risk studies?

The HREA must be used for any multi-jurisdiction research application where ethical approval is being sought under the National Mutual Acceptance (NMA) system.

If I have a site in Victoria, do I still have to complete the Victorian Specific Module (VSM)?

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).

Additional details

Can I convert a NEAF into a HREA?

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

Help and support

Assistance and feedback on the HREA:

Contact the NHMRC if you wish to provide feedback on the HREA questions/question-specific guidance specifically (02 6217 9902 or email help@hrea.gov.au).

Technical problems and assistance with Online Forms:

Contact the Online Forms Helpdesk if you experience any technical issues using Online Forms and require further assistance (02 9037 8404 or email helpdesk@infonetica.net)

For more information:

For general questions, you may contact the NSW Health Research Ethics and Governance Unit (02 9461 7344 or email researchethics@doh.health.nsw.gov.au).

Screenshot of HREA sections, from Online Forms website:

SECTION	QUESTION NUMBER
INTRODUCTION	Q1.0
HREC DIRECTORY	HREC Directory
PROJECT OVERVIEW	Q1.1-Q1.8
PROJECT TEAM	Q1.9
DISCLOSURE OF INTERESTS	Q1.10
RESTRICTIONS	Q1.11
EVALUATIONS	Q1.12-Q1.14
LOCATION	Q1.15-Q1.16
METHODS	Q1.17
PARTICIPANTS	Q1.18-Q1.19
METHOD SPECIFIC	Method specific
ACTION RESEARCH	M1.1-M1.3
BIOSPECIMEN ANALYSIS RESEARCH	M2.1-M2.8
DATA LINKAGE RESEARCH	M3.1-M3.3
ETHNOGRAPHIC RESEARCH	M4.1
EPIDEMIOLOGICAL RESEARCH	M5.1
INTERVENTIONAL/CLINICAL TRIALS RESEARCH	M6.1-M6.3
OBSERVATIONAL RESEARCH	M7.1-M7.4
SURVEY/INTERVIEW/FOCUS GROUP RESEARCH	M8.1-M8.5
TEXTUAL ANALYSIS RESEARCH	M9.1
PARTICIPANT SPECIFIC	Participants specific
PREGNANT WOMEN AND HUMAN FETUS	P1.1-P1.7
CHILDREN AND YOUNG PEOPLE	P2.1-P2.5
PEOPLE HIGHLY DEPENDENT ON MEDICAL CARE WHO MAY BE UNABLE TO GIVE CONSENT	P3.1-P3.3
PEOPLE WITH A COGNITIVE IMPAIRMENT, AN INTELLECTUAL DISABILITY, OR A MENTAL ILLNESS	P4.1-P4.4
PEOPLE IN DEPENDENT OR UNEQUAL RELATIONSHIPS	P5.1
PEOPLE WHO MAY BE INVOLVED IN ILLEGAL ACTIVITIES	P6.1-P6.4
PEOPLE IN OTHER COUNTRIES	P7.1-P7.8
ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES	P8.1-P8.3
PROJECT DETAILS	Project details
RECRUITMENT	Q2.1.1-Q2.1.2 Q2.1.M1.1-Q2.1.M1.2 2.1.M7.1-2.1.M7.2
CONSENT	Q2.2.1-Q2.2.8 Q2.2.M5.1-Q2.2.M5.2 Q2.2.P2.1-Q2.2.P2.5 Q2.2.P3.1-Q2.2.P3.2 Q2.2.P4.1-Q2.2.P4.2 Q2.2.P6.1
RISK	Q2.3.1-Q2.3.2 Q2.3.P5.1
BENEFIT	Q2.4.1-Q2.4.3
DATA AND PRIVACY	Q3.1-Q3.8 Q3.9-Q3.18
GENERATE HREA DOCUMENT	Generate HREA Document
DOCUMENTS	Q4.1-Q4.2
HREC	Q4.3-Q4.6
DECLARATIONS	Declarations