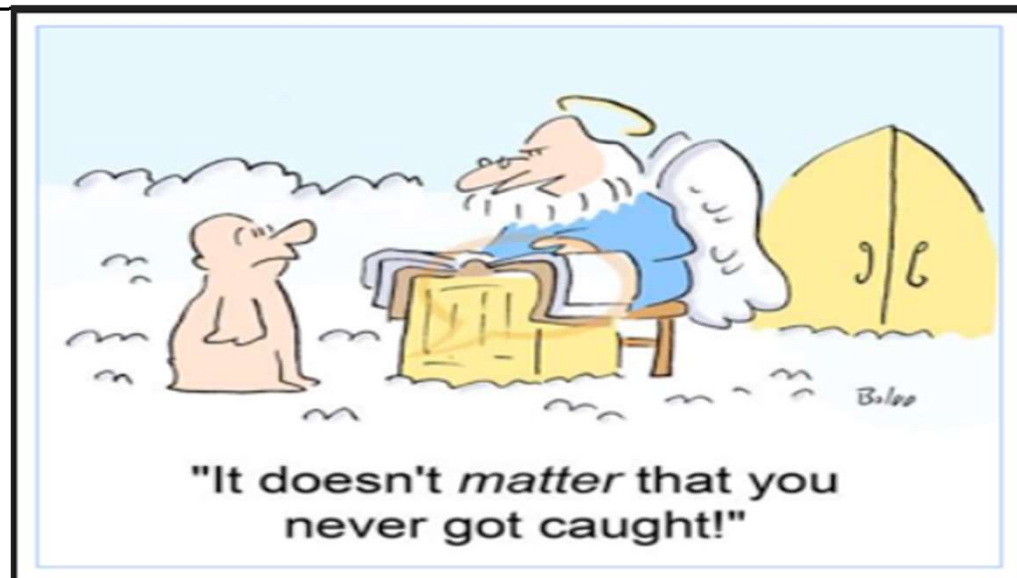

Human Research Ethics Information session

Dr. Shirin Jamarani, Office of Research Ethics



What is human research?

Research conducted **with** or **about** people, or **their data** or **tissue**. Per the *National Statement on Ethical Conduct in Human Research* (updated 2018) human participation includes the involvement of human beings in the following activities:

- surveys, interviews or focus groups;
- psychological, physiological or medical testing or treatments;
- observation by researchers;
- having their personal documents or other materials accessed;
- collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumor and other biopsy specimens) or their exhaled breath, and;
- their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database being accessed.

You MUST have Ethics approval BEFORE conducting research!

National Statement on Ethical Conduct in Human Research

2007 (Updated 2018)

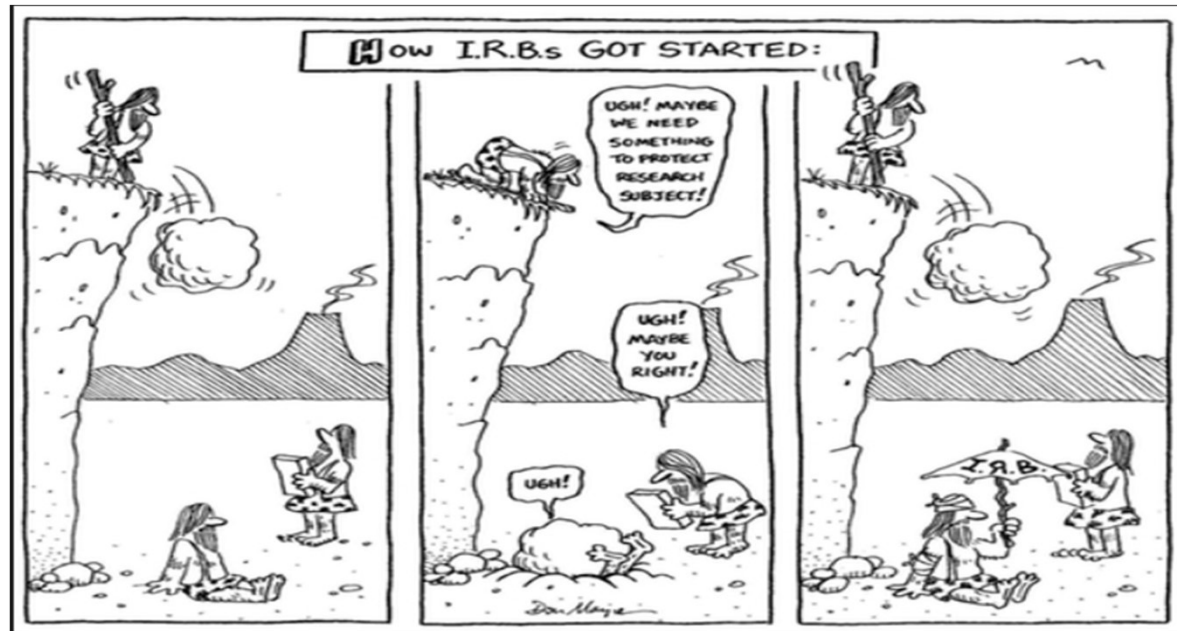
The [National Statement](#), following a wide consultation with researchers and the public, is written by a panel of experts;

- National Health And Medical Research Council (NHMRC)
- Australian Research Council (ARC)
- Universities Australia

The National Statement is “[...oriented to something more fundamental than ethical ‘do’s’ and ‘don’ts’ – namely, an **ethos** that should permeate the way those engaged in human research approach all that they do in their research.” (National Statement, p. 3)

An HREC or LNR sub-committee, based on the criteria set by the National Statement and any other relevant guideline, determines whether a Human Research study can be **ethically approved**.

Why Ethics approval?



- Research merit and integrity, Justice, Beneficence, Respect
- To protect the rights and welfare of Human participants
- To minimise the potential for claims of negligence made against researchers and/or the university

What is Ethics?

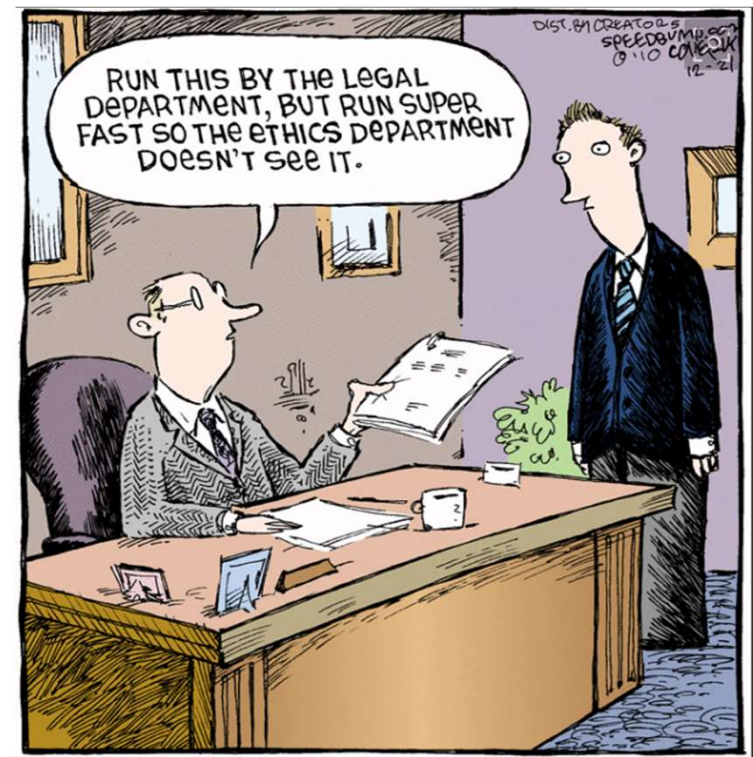
Moral principles that govern a person's behaviour or conducting of an activity.

(Oxford dictionary)

Ethical research is a process

Research design and planning

- Collection of data
 - Choice of participants, Consent process
- Analysis of data
- Dissemination of findings
 - infringement of privacy, confidentiality, or ownership



Exemption from Review process

Exemption from Review process

The National Statement (5.1.22) states that “Institutions may choose to exempt from ethical review research that:

1. is negligible risk research, **AND**
2. involves the use of existing collections of data or records that contain only **non-identifiable** data about human beings.”

Some Quality Assurance or Evaluation Activities (provided they do not constitute the definition of research).

Applying for exemption: <http://www.uq.edu.au/research/integrity-compliance/>

UQ policy and procedures: <http://ppl.app.uq.edu.au/content/4.20.07-requesting-exemption-human-research-ethics-review>

What is risk?

A risk is a potential for **harm, discomfort** or **inconvenience**. It involves:

- the likelihood that a harm (or discomfort or inconvenience) will occur; and
- the severity of the harm, including its consequences

Harm (*HREC review*)

Physical harms: including;

- E.g. injury, illness, pain;

Psychological harms: including;

- feelings of worthlessness, distress, guilt, anger or fear (e.g. related to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease);
- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;

Social harms: including;

- damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;

Economic harms: including;

- the imposition of direct or indirect costs on participants;

Legal harms: including;

- discovery and prosecution of criminal conduct.

Low and Negligible Risk (LNR review)

LNR: A project in which the only foreseeable risk is one of discomfort or inconvenience. If there is any chance that the research may result in anything more serious than discomfort, the research cannot be called low risk.

Discomfort: less serious than harm is discomfort, which can involve body and/or mind. For example;

- minor side-effects of medication,
- the discomforts related to measuring blood pressure,
- anxiety induced by an interview.

Inconvenience: less serious again is inconvenience. For example;

- filling in a form,
- participating in a street survey,
- giving up time to participate in research.

HREC is *always* required for ...

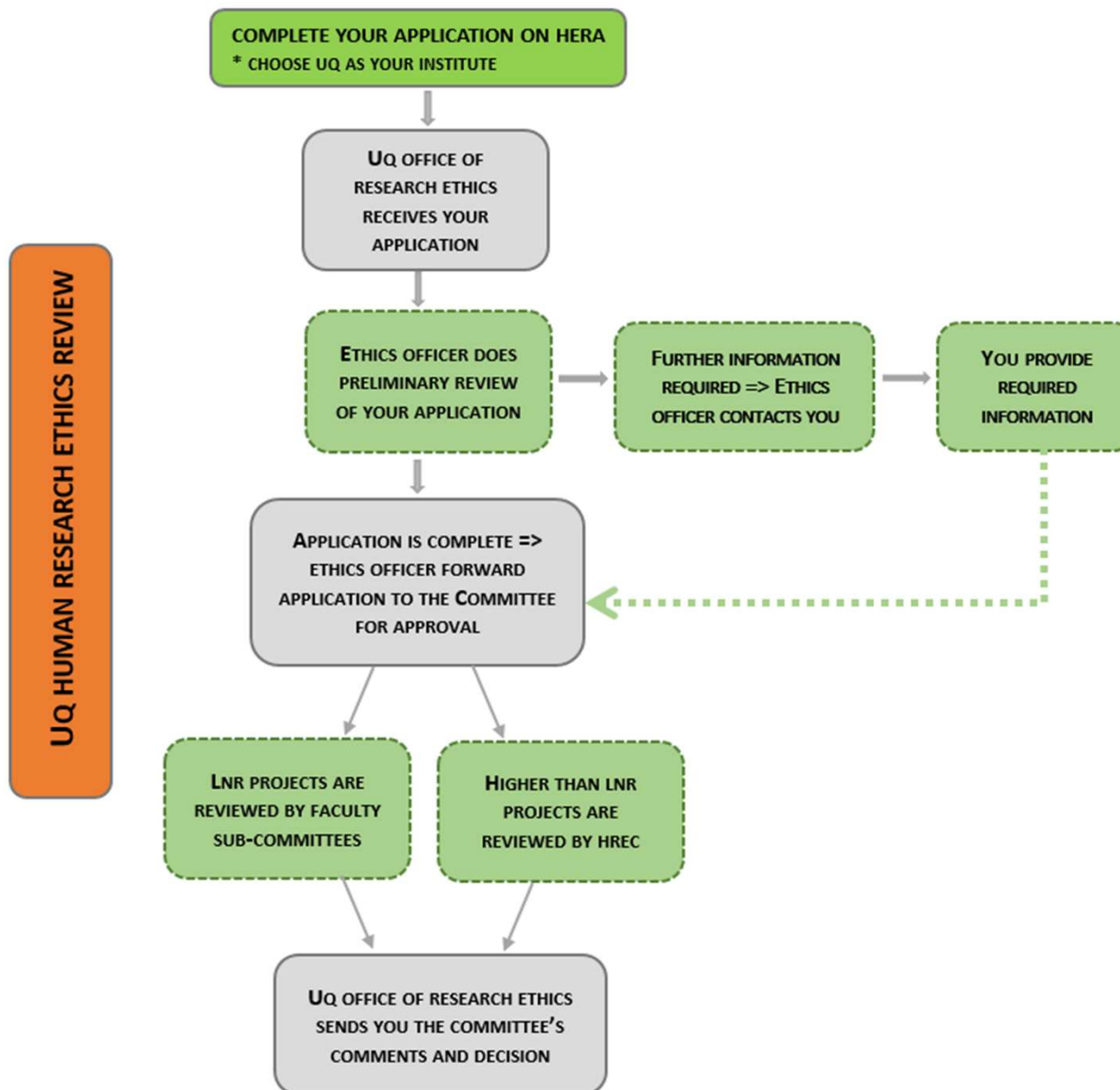
Projects with greater than low risk **or** projects involving participants from any of the following categories:

- Women who are pregnant and the human foetus (Ch. 4.1)
- People highly dependent on medical care who may be unable to provide consent (Ch. 4.4)
- People with a cognitive impairment, an intellectual disability, or a mental illness (Ch. 4.5)
- People who may be involved in illegal activities (Ch. 4.6)
- Aboriginal and Torres Strait Islander Peoples (Ch. 4.7)
- Interventions and Therapies, including clinical-and non-clinical trials and innovations (Ch. 3.3)
- Human Genetics (Ch. 3.5)

Targeted, Likely/Foreseeable and Coincidental Participant Recruitment

Review process

HREC or LNR sub-committee



Human Research Ethics Committee (HREC)

At least 8 people on an HREC;

- equally men and women;
- at least 1/3 of the members external to the reviewing institution
- members are from different categories;
 - a committee chair
 - at least 2 lay people, a man and a woman (not themselves researchers, no affiliation to the research institution)
 - at least 1 person with experience in counselling or treatment of people;
 - at least 1 person who performs pastoral care in the community, e.g. an Aboriginal elder or minister of religion;
 - a lawyer;
 - at least 2 researchers.



Layman Language!

Ethics considerations

2 categories;

- relating to ***informed consent (PICF)***, and
- relating to;
 - risks and benefits;
 - Selection and recruitment of participants; and
 - data monitoring, privacy, and confidentiality.
 - special protections for ***vulnerable groups*** of participants;
 - Pregnant women and the Human fetus
 - Children and Young people
 - People in dependent and unequal relationships
 - People highly dependent on medical care who maybe unable to give consent
 - People with cognitive impairment, an intellectual disability, or a mental illness
 - People who may be involved in illegal activities
 - Aboriginal and Torres Strait Islander peoples
 - People in other countries

Basic Principles

4 principles must always be considered in human research:

1. Research Merit & Integrity
2. Justice (equitable selection of participants)
3. Beneficence (Risk and Benefits)
4. Respect (for participants → informed consent)

Research Merit & Integrity

- The design will meet the project's aim and produce generalizable knowledge
- The research team have appropriate qualifications, skills and experiences
- Appropriate facilities & resources are available to conduct the research
- Appropriate plan for dissemination of results

Justice (equitable selection of participants)

- Participants are selected for reasons directly related to the problem being studied **NOT** easy availability or their compromised position.
- There is a fair distribution of the risks and benefits of research. Not be fair if one group bears the **risks** of research while another group reaps its **benefits**.

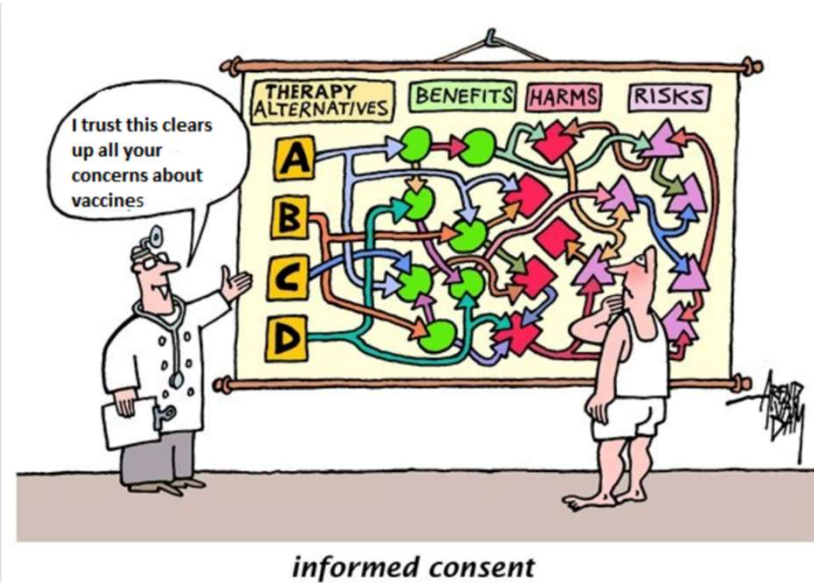


Beneficence (Risk and Benefit)

- Risks are identified/mitigated and justified by the benefits
- Is there another way to obtain the same knowledge but with lower risks to participants?

Minimization of the Risks to participants

- **Mitigating risk**
 - While risks must be minimized, the study must nonetheless be accomplished.
- **Risks and Benefits**
 - Research is ethically acceptable only when its potential benefits justify any risks involved in the research. Benefits of research may include;
 - direct benefits to the research participants, their families or community,
 - gains in knowledge, insight and understanding,
 - improved social welfare and individual wellbeing,
 - gains in skill or expertise for individual researchers/teams/ institutions.



Respect (Voluntary informed consent)

An agreement voluntarily provided by a potential research participant following an explanation of all relevant information needed to make a decision about participating in a study.

Voluntary informed consent

Voluntary Informed consent:

- Information (purpose, methods, demands, risks and potential benefits),
- Comprehension (jargon, Lang. barrier, education, maturity, cultural issues),
- Voluntariness.

Respect for participants :

- Individuals should be treated as autonomous, and
- Individuals with diminished autonomy (i.e. vulnerable groups) should be entitled to additional protections.

Waiving Consent

Withdrawal

Even with informed consent participants should be aware that;

- they can withdraw at any time without explanation → ***if not, why?***
- there would not be any degree of persuasion or coercion for them to continue participating
- they would not be negatively affected if they choose to stop participating

These should be clearly stated in the consent form!

The value of respect in human research ethics: a conceptual analysis and a practical guide

I. J. Pieper · C. J. H. Thomson

Published online: 13 January 2015
© Monash University 2015

Abstract In order to continue to maintain public trust and confidence in human research, participants must be treated with respect. Researchers and Human Research Ethics Committee members need to be aware that modern considerations of this value include: the need for a valid consenting process, the protection of participants who have their capacity for consent compromised; the promotion of dignity for participants; and the effects that human research may have on cultures and communities. This paper explains the prominence of respect as a value when considering the ethics of human research and provides practical advice for both researchers and Human Research Ethics Committee members in developing respectful research practices.

Keywords Human research ethics · Human Research Ethics Committees (HREC) · IRB · Respect

Internet research

- Internet as a *tool for research*
E.g. Surveys (Qualtrics, Survey Monkey, etc.)
- Internet as a *locate or venue of research*

Public vs. Private data

- Publicly available data

Information that is legally available to any internet user, without special authorization or access permission.

- Private data

Identifiable information that is available only with a subject's permission, or by using a password or other access mechanism under the subject's control.

Private information is considered *identifiable* if the identity of the subject is or may be ascertained.

Privacy in Internet research

Problematic for researcher and participant

- Is the space being researched seen as private by its users?
Are they aware they are being observed?
What is the researcher's role?
- How do researchers ensure their participants really are anonymous?
IP Addresses are (usually) traceable
Tweets may contain identifiers....

Core considerations

- **Preserving privacy and confidentiality**

E.g. if you were to quote a Twitter post verbatim, the user can then be identified with a search engine.

- **Consent related issues**

Verifying identification

Ensuring comprehension

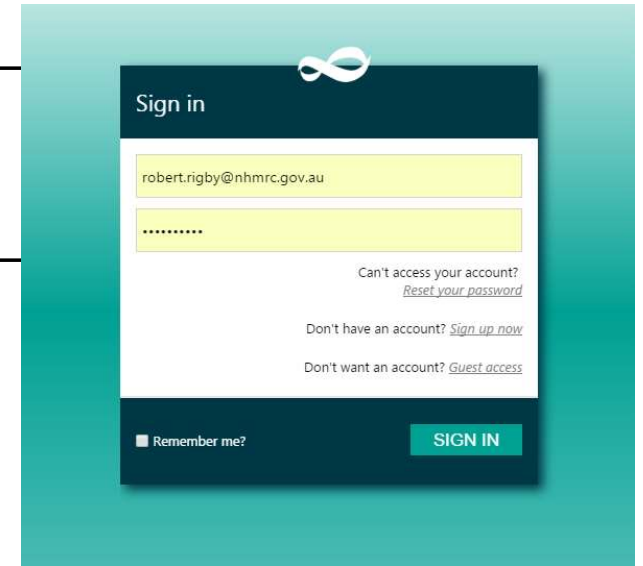
Obtaining appropriate documentation when needed

- **Terms of service**

Who owns the data you create in a social networking site?

Most common issues

- Use latest version of your browser
- Try a different browser (Google Chrome)
- Submitted applications are saved for 90 days on the server
- After 90 days the data is wiped – NHMRC do not keep a copy!
- If you need to update a field in your application or add a document **DO NOT** submit a new application. Call the ethics office first to see if they can fix it for you.



Common problems in applications

- Missing signatures;
 - In case of student research, **the supervisor is ALWAYS the Lead investigator.**
As the signatory of the application, the supervisor is responsible for;
 - Briefing students about the ethics requirements when preparing the project
 - Guiding the student in the completion of the application
 - Guiding the student in the ethical conduct of your research
 - Monitoring the project
- Read each question in the application and answer carefully.
 - Eliminate guesswork! If any questions contact Office of Research Ethics.
 - Avoid providing information not directly relevant to the question.
 - **Be clear, concise and accurate!**
- **Risks not identified!**
- **Conflict of interest not identified/disclosed!**

- Submit all Supporting documentation
 - **Project description/Protocol**
 - Participant Information Sheet and Consent form (translations)
 - Questionnaire/survey (translations)
 - Any other relevant document
- Use lay-language (non-technical language) in describing your project
- Use a consistent system to name all supporting documents
 - e.g. Name-Consent form-v1-date
- Avoid giving your personal mobile phone numbers in Participant Information and Consent Forms. Give a Departmental landline or a project-specific mobile phone number.
- Meet submission deadlines.
- ***Proof-read your application.***
- Follow the committee's advice: this is the ***fastest*** way of gaining clearance!

Need Help?

Applying for Human Ethics Clearances

- <http://uq.edu.au/research/integrity-compliance/>

Forms and resources

- <http://www.uq.edu.au/research/integrity-compliance/human-forms-resources>

(HREC) Human Ethics Unit Coordinator


- humanethics@research.uq.edu.au

LNR coordinator


- Michael Tse BELLNR@UQ.EDU.AU

How to share the HREA application

You first need to create an application on HREA. Then once you log in, you will see your application(s).



Australian Government
National Health and Medical Research Council



01:59:06
Logged in [Maryam Jamarani]

NHMRC

Home

HREA Portal

Welcome to the NHMRC HREA Online Portal

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 a new one, or click the 'Upload application' button to resume a downloaded application.

[+ New application](#)[Upload application](#)

Click on the "Application" button

The screenshot shows the NHMRC HREA Portal interface. At the top, there is a header with the Australian Government logo and the text 'Australian Government National Health and Medical Research Council'. Below this is a dark blue navigation bar with the NHMRC logo and several icons: a person icon, a list icon, a gear icon, and a question mark icon. The 'Applications' button, represented by the list icon, is highlighted with a red arrow. Below the navigation bar, the main content area is titled 'HREA Portal' and includes a welcome message: 'Welcome to the NHMRC HREA Online Portal'. A section titled 'Top 5 In Progress applications' contains a light blue box with instructions: '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.' Below this box are two buttons: '+ New application' and 'Upload application'. At the bottom, there is a table with the following columns: Identifier, Title, Status, Round, and Stage. The table lists two applications: MJ00972 (Info session, In Progress, Human Research Ethics Application, Stage 1) and MJ00940 (Shirin Test Application, In Progress, Human Research Ethics Application, Stage 1).

Australian Government
National Health and Medical Research Council

NHMRC

Home

Applications

HREA Portal

Welcome to the NHMRC HREA Online Portal


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 a new one, or click the 'Upload application' button to resume a downloaded application.


+ New application Upload application

Identifier	Title	Status	Round	Stage
MJ00972	Info session	In Progress	Human Research Ethics Application	Stage 1
MJ00940	Shirin Test Application	In Progress	Human Research Ethics Application	Stage 1

You now see 3 vertical dots next to your application code.



Australian Government
National Health and Medical Research Council



01:58:13
Logged in [Maryam Jamarani]

NHMRC

[Home](#) | [Applications](#)

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.


[+ New application](#) [Upload application](#)

Show 10 entries

Search:

	Identifier	Title	Version	Status	Owner	Round	Stage	Status
▶ ⋮	MJ00972	Info session	1	In Progress	Maryam Jamarani	Human Research Ethics Application	Stage 1	Open
▶ ⋮	MJ00940	Shirin Test Application	1	In Progress	Maryam Jamarani	Human Research Ethics Application	Stage 1	Open

Click on the 3 dots and a new window opens.
Click on "invite user to register or share application".



Australian Government
National Health and Medical Research Council

01:58:04
Logged in [Maryam Jamarani]

NHMRC

Home | Applications

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.

+ New application

Upload application

Show 10

Search:

	Title	Version	Status	Owner	Round	Stage	Status
⋮	Intervention for...	1	In Progress	Maryam Jamarani	Human Research Ethics Application	Stage 1	Open
⋮	Intervention for...	1	In Progress	Maryam Jamarani	Human Research Ethics Application	Stage 1	Open

Application information

Copy application

Download data file

Options

Invite user to register or share application

Rename application

Delete application

Create change

UNIVERSITY
NSLAND

A new window opens. In the Username box type in the email address of the person with whom you want to share the application. Follow the prompts.

The screenshot shows the NHMRC Applications page. A modal titled 'Invite user to register or share' is open in the center. The modal contains the following elements:

- Invite or Share** section: A text prompt asking the user to enter a username to send an invitation or share access. It notes that if the user does not exist, they will receive an email invitation, and if they download/upload a copy, they will control that copy.
- Username** field: A text input box for entering the username.
- Share** checkbox: A checkbox labeled 'Share'.
- Application Selection**: A dropdown menu showing 'MJ00972 - Info session' and a 'View' button.
- + Add** button: A green button to add the user.
- Assigned users** section: A heading followed by the text 'The list of users currently assigned to this application are listed below.'
- Message box**: A light blue box with an information icon stating 'There are currently no users assigned to this application.'

The background page shows the NHMRC logo, navigation links (Home, Applications), and a list of applications. The top right corner shows a clock (01:56:54) and a user login status (Logged in [Maryam Jamarani]).