
Human Research Ethics Information session

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Outline

- Human Research
- Low and Negligible Risk (LNR) research
- Exemptions
- Reviews process
- Ethical principles of Human research
- Applying for research ethics approval

National Statement on Ethical Conduct in Human Research

The [National Statement](#) is written by a panel of experts;

- National Health And Medical Research Council (NHMRC)
- Australian Research Council (ARC)
- Australian Vice-chancellors' Committee (AVCC)

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 2007, 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 approved.

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 May 2015) 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(in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database being accessed.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 Human research!

What is Ethics?

Moral principles that govern a person's behaviour or conducting of an activity (Oxford dictionary)

How do you translate it into your research design?



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

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.

Discomfort and Inconvenience

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.

Low and Negligible Risk (LNR)

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

Negligible Risk: A project in which there is no foreseeable risk of discomfort or harm and if there is any foreseeable risk, it will not be more than an inconvenience. If there is any chance, no matter how small, that the risk will exceed inconvenience, then the research cannot be classified as being of negligible risk.

Review Process of LNR projects

Exemption from Review process

Exemption

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).

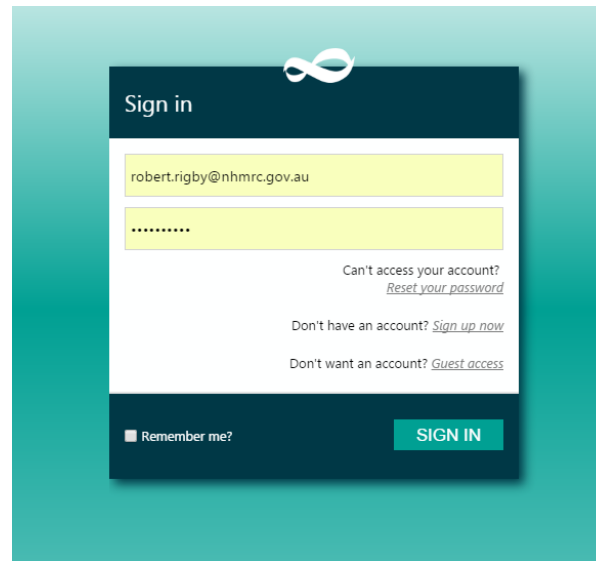
HREC is *always* required for ...

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)*
- *People in other countries (Ch 4.8)*
- *Interventions and Therapies, including clinical-and non-clinical trials and innovations (Ch 3.3)*
- *Human Genetics (Ch 3.5)*

Human Research Ethics Application (HREA)

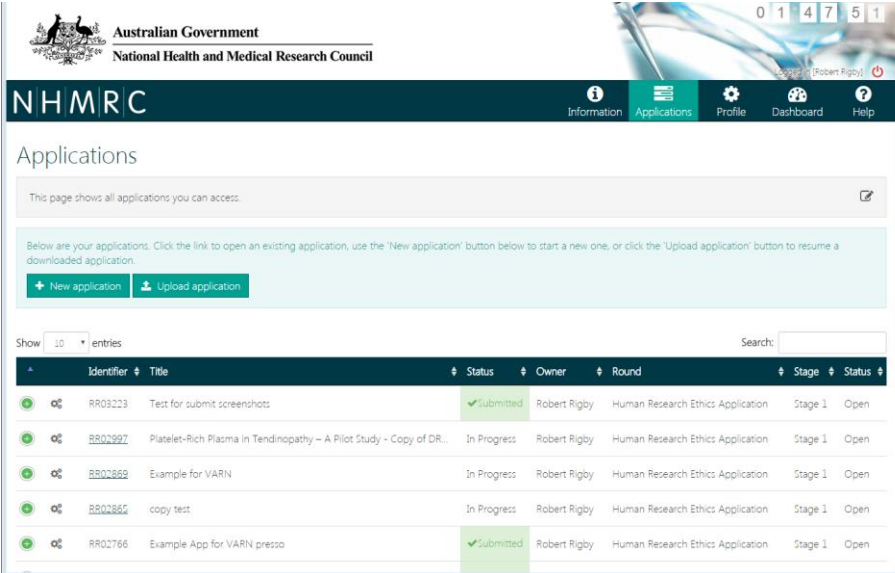
- You will need to sign up for an account if you don't already have one.
- If you would like to take a quick look without signing up, click on Guest Access (no information saved by NHMRC).



The screenshot shows a 'Sign in' form for the NHMRC Human Research Ethics Application (HREA). The form is set against a teal gradient background. At the top, there is a white infinity symbol. The form itself has a dark teal header with the text 'Sign in'. Below this, there are two yellow input fields: the first contains the email address 'robert.rigby@nhmrc.gov.au' and the second contains a masked password '.....'. To the right of the password field, there are three links: 'Can't access your account? [Reset your password](#)', 'Don't have an account? [Sign up now](#)', and 'Don't want an account? [Guest access](#)'. At the bottom of the form, there is a checkbox labeled 'Remember me?' and a teal button labeled 'SIGN IN'.

The HREA

- To start a new application, click on the “Applications” button on the task bar and then “New Application”



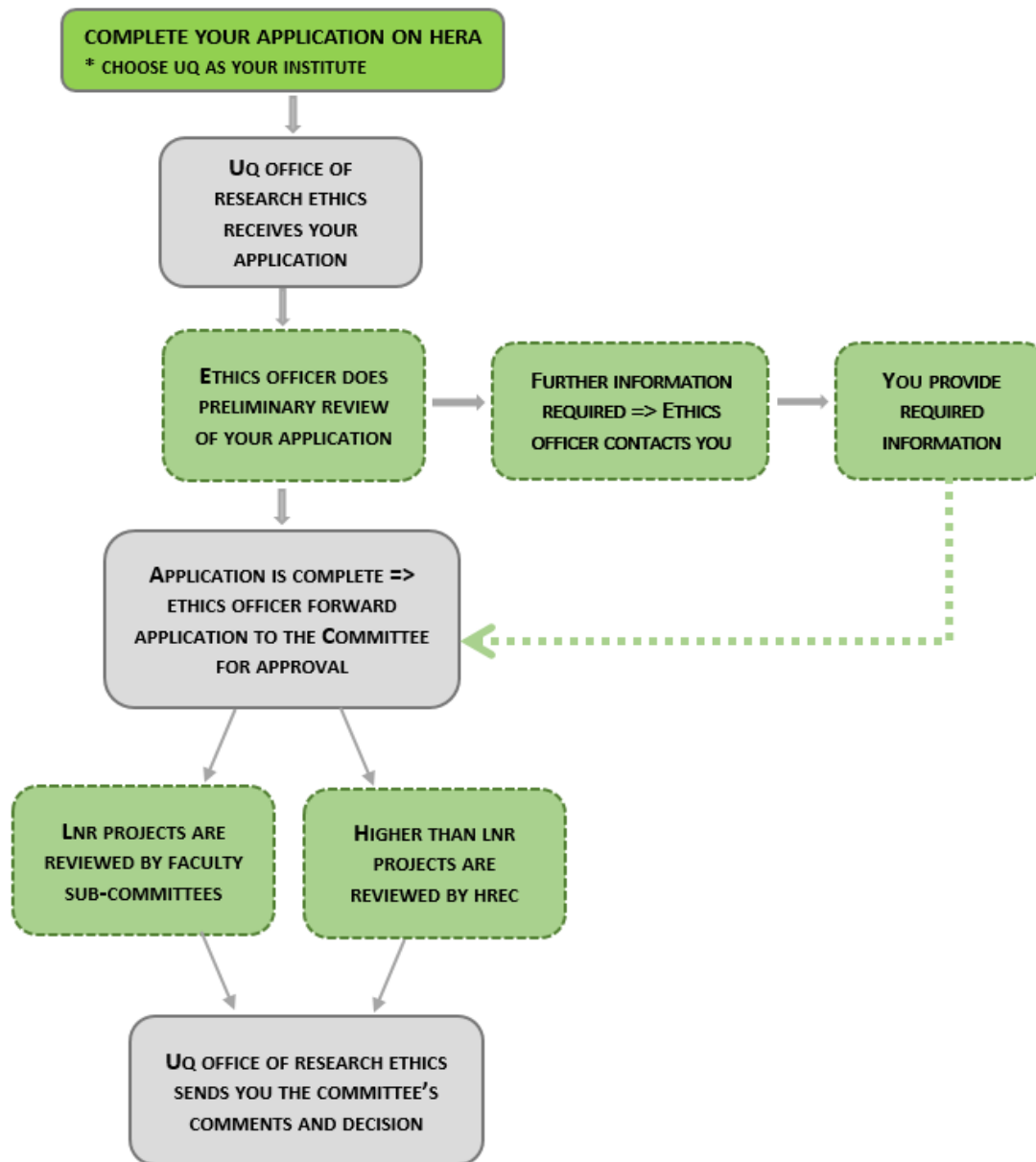
The screenshot shows the NHMRC Applications page. At the top, there is the Australian Government logo and the text "Australian Government National Health and Medical Research Council". Below this is the NHMRC logo and a navigation bar with buttons for Information, Applications, Profile, Dashboard, and Help. The main heading is "Applications". Below the heading, there is a message: "This page shows all applications you can access." and a note: "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." There are two buttons: "+ New application" and "Upload application". Below this is a table of applications. The table has columns for Identifier, Title, Status, Owner, Round, Stage, and Status. The table contains five rows of applications.

Identifier	Title	Status	Owner	Round	Stage	Status
RR03223	Test for submit screenshots	Submitted	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02997	Platelet-Rich Plasma in Tendinopathy - A Pilot Study - Copy of DR...	In Progress	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02852	Example for VARN	In Progress	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02857	copy test	In Progress	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02766	Example App for VARN presso	Submitted	Robert Rigby	Human Research Ethics Application	Stage 1	Open

Review process

HREC or LNR sub-committee

UQ HUMAN RESEARCH ETHICS REVIEW



Human Research Ethics Committee (HREC)

At least 8 people on an HREC;

- equally men and women, and;
- at least a third 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;

- those relating to ***informed consent***, and
- those relating to ***other topics***;
 - risks and benefits;
 - selection 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

Targeted, Likely/Foreseeable and Coincidental Participant Recruitment

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)

Justice (equitable selection of participants)

The fair distribution of the risks and benefits of research. It would not be fair if one group bears the **risks** of research while another group reaps its **benefits**.



Beneficence (Risk and Benefit)

-
- Minimize risks to participants and maximize benefits to participants and/or society.
 - Could there be another way that you could obtain the same knowledge but with lower risks to participants?

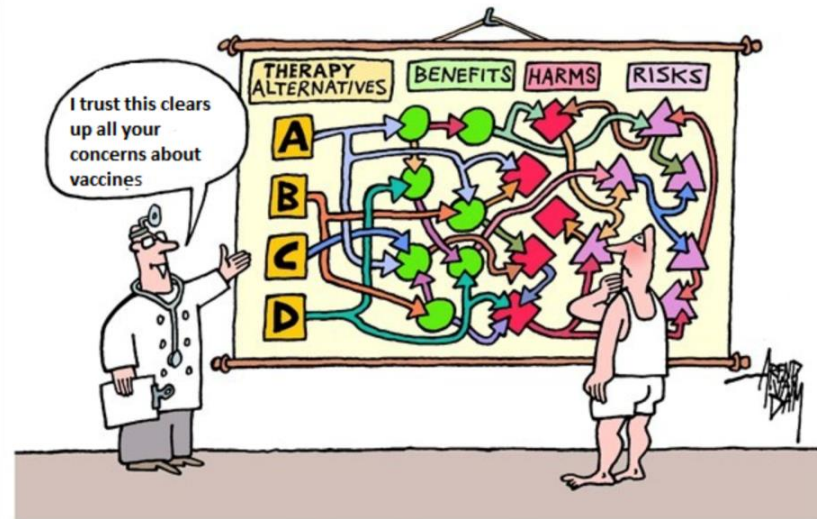
Minimization of the Risks to participants

- **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.



informed consent

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 (non-technical language), and
- 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

The requirement for consent may sometimes be justifiably waived. In this case research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.

‘Limited disclosure’ to participants of the aims and/or methods of research may also sometimes be justifiable. This is because in some human research (for example, in the study of behaviour), the aims of the research cannot be achieved if those aims and/or the research method are fully disclosed to participants. (National Statement p. 22)



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Create change

Withdrawal

Even with informed consent participants should be aware that;

- they can withdraw at any time without explanation
- 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

This should be clearly stated in the consent form!

Applying for Ethical clearance

The HREA

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Create change

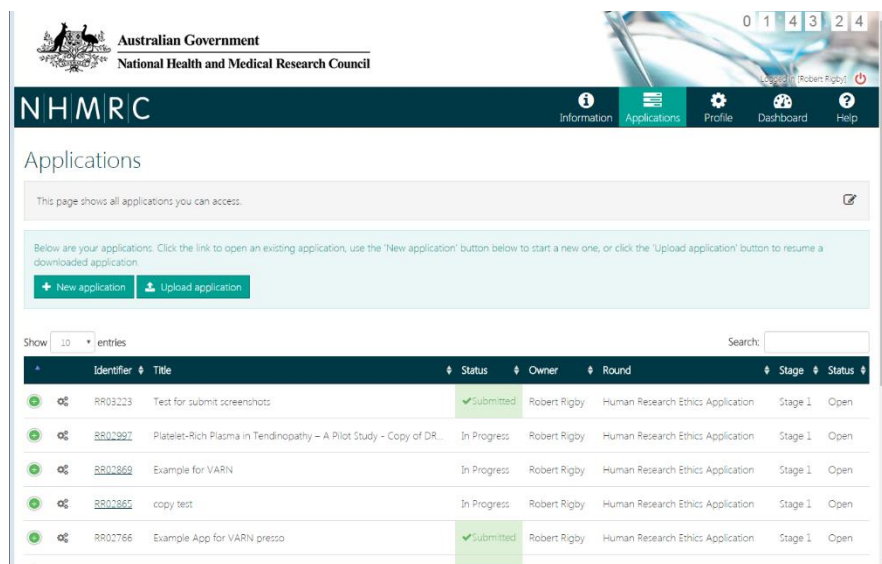
The HREA

- Page with magnifying glass = download preview PDF, RTF & attachments
- Down arrow = save application to server
- Left Arrow = move back
- Right Arrow = move forward

The screenshot shows the NHMRC HREC Directory application interface. The top navigation bar includes links for Information, Applications (active), Profile, Dashboard, and Help. The user is logged in as Robert Rigby. The main content area is titled "RR02869 - Example for VARN". On the left is a sidebar menu with options: Introduction, HREC Directory, Project Overview (selected), Project Team, Disclosure of Interests, Restrictions, Evaluations, Location, Methods, Participants, Project Details, Participant Specific, Recruitment, Consent, Risk, Benefit, Data and Privacy, Finalise and Submit, Upload, Declaration, HREC, and Download and Submit. The "Project Overview" section contains three questions: Q1.1 (Project title), Q1.2 (Summary of research project), and Q1.3 (Where research will be conducted). Each question has a text input field and a list of instructions. At the bottom, there is a rich text editor with a toolbar and a preview area showing the text "Lots of information here!" with a bulleted list: "And", "some", and "dot".

The HREA

- Moving from field to field will auto-save your application.
- If working in a large free text field, however, you should manually save periodically (down arrow)
- Time out counter is always at top right of screen

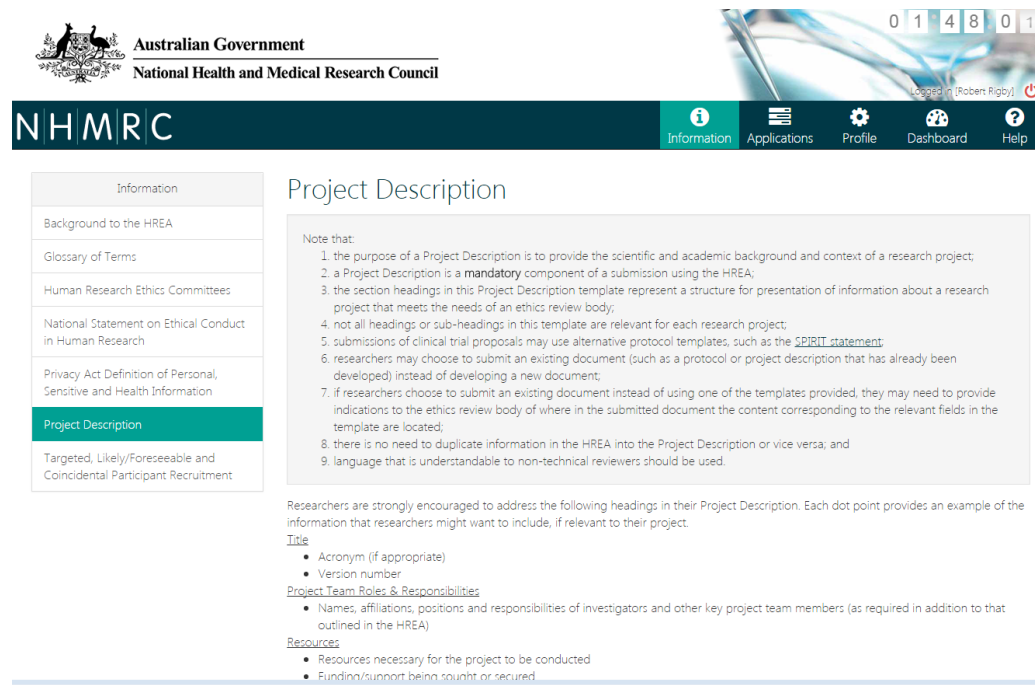


The screenshot shows the NHMRC (National Health and Medical Research Council) Applications page. The header includes the Australian Government logo and the NHMRC name. A navigation bar contains links for Information, Applications (active), Profile, Dashboard, and Help. A timeout counter in the top right corner shows 01:43:24. The main content area is titled 'Applications' and includes a message: 'This page shows all applications you can access.' Below this, instructions state: '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.' There are two buttons: '+ New application' and '+ Upload application'. A table lists the applications with columns for Identifier, Title, Status, Owner, Round, Stage, and Status. The table contains five entries, all owned by Robert Rigby and at Stage 1.

Identifier	Title	Status	Owner	Round	Stage	Status
RR03223	Test for submit screenshots	Submitted	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02997	Platelet-Rich Plasma in Tendinopathy – A Pilot Study - Copy of DR...	In Progress	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02669	Example for VARN	In Progress	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02685	copy test	In Progress	Robert Rigby	Human Research Ethics Application	Stage 1	Open
RR02766	Example App for VARN presso	Submitted	Robert Rigby	Human Research Ethics Application	Stage 1	Open

The HREA

- A **Project Description (protocol)** is required for each application.



The screenshot shows the NHMRC website interface. At the top, the Australian Government logo and NHMRC name are visible. A navigation bar includes links for Information, Applications, Profile, Dashboard, and Help. A sidebar on the left lists various information resources, with 'Project Description' highlighted. The main content area is titled 'Project Description' and contains a 'Note that:' section with nine numbered points. Below this, a paragraph encourages researchers to address specific headings in their Project Description, followed by bulleted examples for 'Title', 'Project Team Roles & Responsibilities', and 'Resources'.

Australian Government
National Health and Medical Research Council

0 1 4 8 0 1

Information Applications Profile Dashboard Help

Information

- Background to the HREA
- Glossary of Terms
- Human Research Ethics Committees
- National Statement on Ethical Conduct in Human Research
- Privacy Act Definition of Personal, Sensitive and Health Information
- Project Description**
- Targeted, Likely/Foreseeable and Coincidental Participant Recruitment

Project Description

Note that:

1. the purpose of a Project Description is to provide the scientific and academic background and context of a research project;
2. a Project Description is a **mandatory** component of a submission using the HREA;
3. the section headings in this Project Description template represent a structure for presentation of information about a research project that meets the needs of an ethics review body;
4. not all headings or sub-headings in this template are relevant for each research project;
5. submissions of clinical trial proposals may use alternative protocol templates, such as the [SPIRIT statement](#);
6. researchers may choose to submit an existing document (such as a protocol or project description that has already been developed) instead of developing a new document;
7. if researchers choose to submit an existing document instead of using one of the templates provided, they may need to provide indications to the ethics review body of where in the submitted document the content corresponding to the relevant fields in the template are located;
8. there is no need to duplicate information in the HREA into the Project Description or vice versa; and
9. language that is understandable to non-technical reviewers should be used.

Researchers are strongly encouraged to address the following headings in their Project Description. Each dot point provides an example of the information that researchers might want to include, if relevant to their project.

Title

- Acronym (if appropriate)
- Version number

Project Team Roles & Responsibilities

- Names, affiliations, positions and responsibilities of investigators and other key project team members (as required in addition to that outlined in the HREA)

Resources

- Resources necessary for the project to be conducted
- Funding/support being sought or secured

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 and they will fix it for you.

Common problems in applications

- Proof-read your application!
- Read each question in the application and answer carefully. Avoid providing information not directly relevant to the question.
- Be sure to use lay-language (non-technical language) in describing your project
- **Don't hide the risks!**
- Submit all Supporting documentation
 - Project description/Protocol
 - Participant Information Sheet and Consent form (translations)
 - Questionnaire/survey (translations)
 - Any other relevant document
- Use a consistent system to name all supporting documents
 - e.g. Name-Consent form-v1-date
- **Meet submission deadlines!**
- Make sure you have all the required signatures.
 - In case of student research, **the supervisor is ALWAYS the Lead investigator!**
 - List the professional email addresses of the research team.

- Follow carefully the committee's advice: this is the fastest way of gaining clearance.
 - Do not duplicate your application on HREA. Make a new version and call it e.g. V1 or V2
 - Provide “track changed” and “clean copy”

Eliminate guesswork! If any questions contact Office of Research Ethics.

Need Help?

Applying for Human Ethics Clearances

- <http://www.uq.edu.au/research/integrity-compliance/human-ethics-clearances>

Human Ethics Unit Coordinator humanethics@research.uq.edu.au

LNR projects

- BEL Faculty BELLNR@UQ.EDU.AU.
- EAIT Faculty (including SMI and AIBN) EAITLNR@UQ.EDU.AU.
- HABS Faculty HABSLNR@UQ.EDU.AU.
- HASS Faculty (including ISSR) HASSLNR@UQ.EDU.AU.
- MEDICINE Faculty (including QBI and CAI) MEDICINELNR@UQ.EDU.AU.
- SCIENCE Faculty (including QGCI, QAAFI and IMB) SCIENCELNR@UQ.EDU.AU.

Some Essential Documentation

National Statement on Ethical Conduct in Human Research (2007)
Updated May 2015

<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

UQ Policy: Responsible Conduct of research (4.20.02)

<https://ppl.app.uq.edu.au/content/4.20.02-responsible-conduct-research>

UQ Policy, Research Data Management (4.20.06)

<http://ppl.app.uq.edu.au/content/4.20.06-research-data-management>

UQ Procedure, Exemption from Human Research Ethics Review
(4.20.07)

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



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