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(in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database being accessed.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

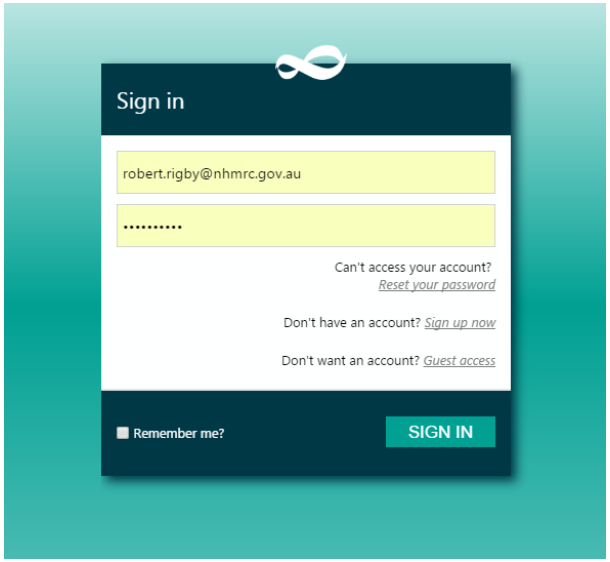
HREC is *always* required for …

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)*

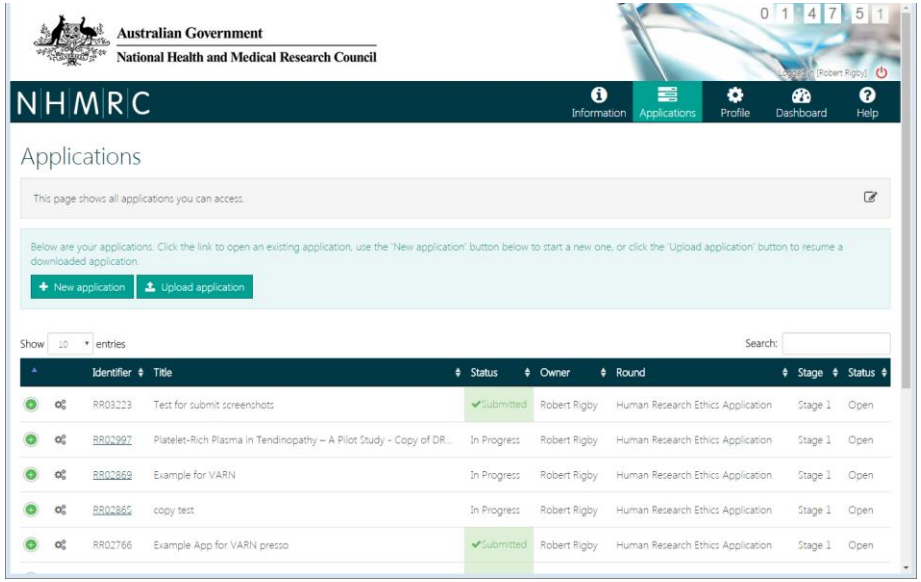
Human Research Ethics Application (HREA)

- 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 HREA

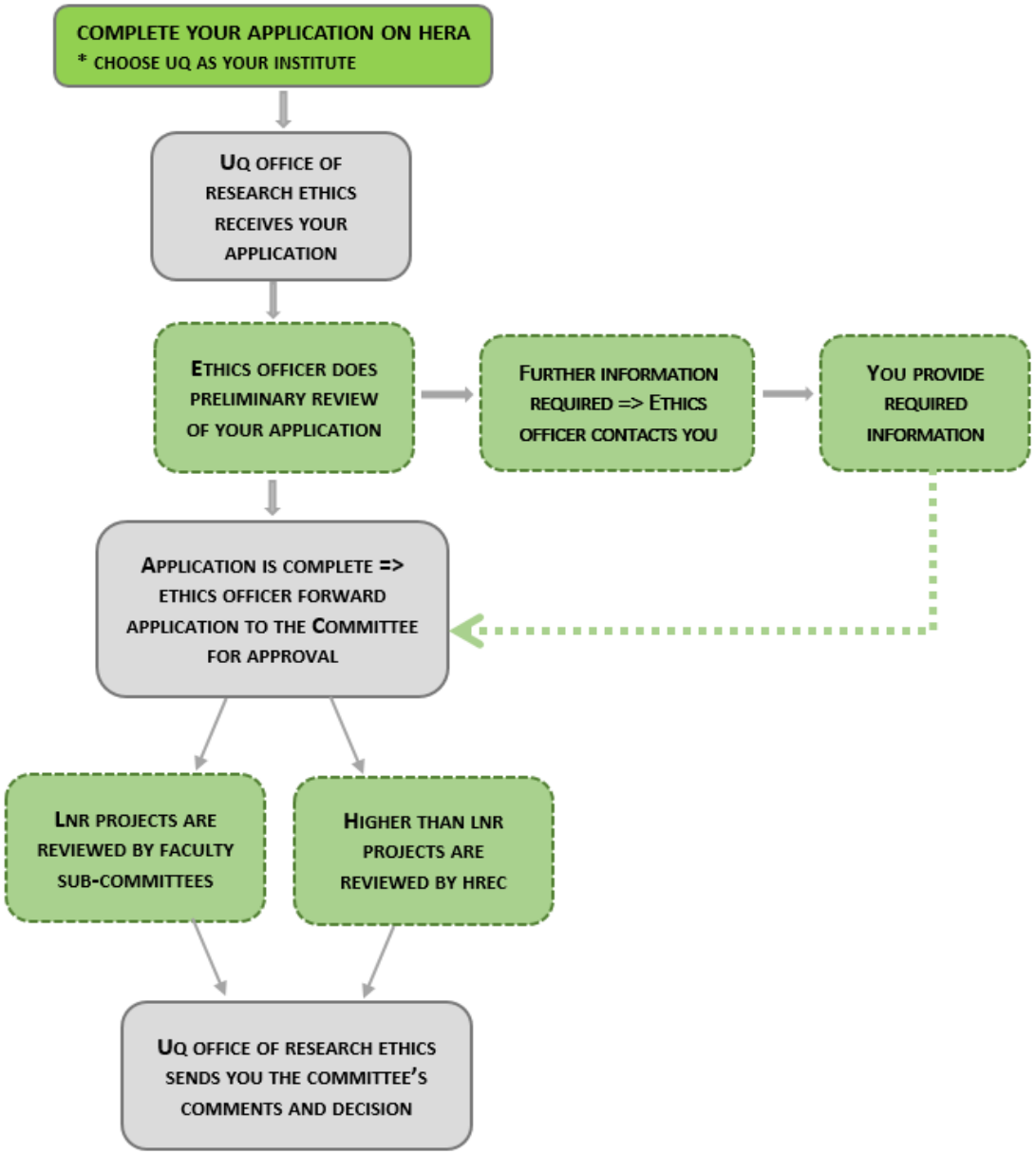
- To start a new application, click on the “Applications” button on the task bar and then “New Application”



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)

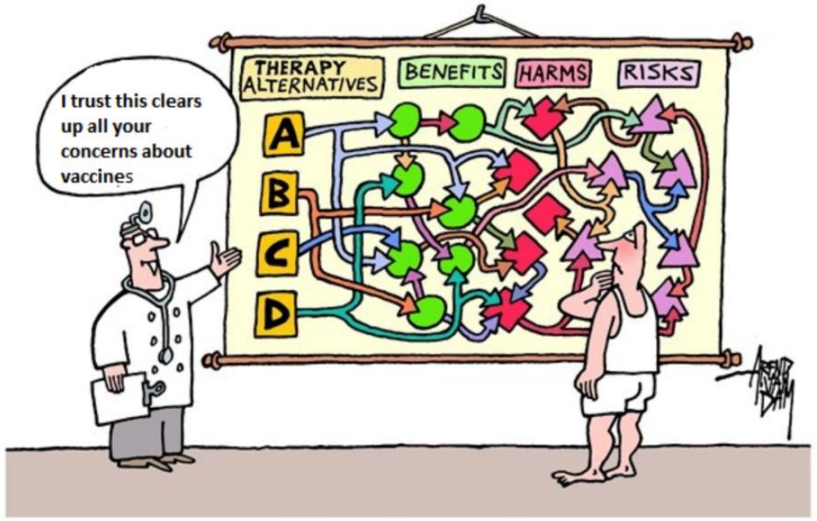
The fair distribution of the risks and benefits of research. It would not be fair if one group bears the **risks** of research while another group reaps its **benefits**.

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)

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

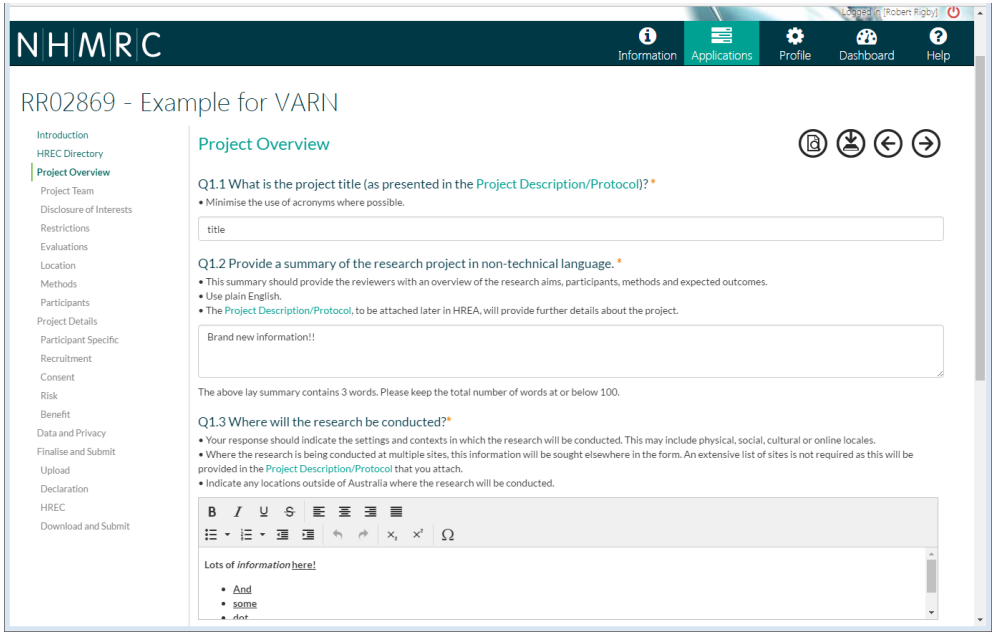
This should be clearly stated in the consent form!

Applying for Ethical clearance

The HREA

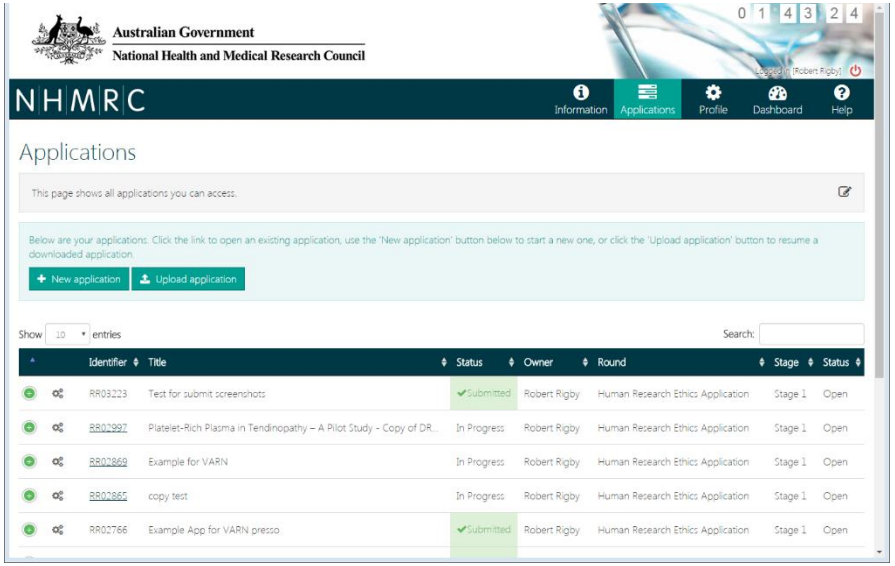
The HREA

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



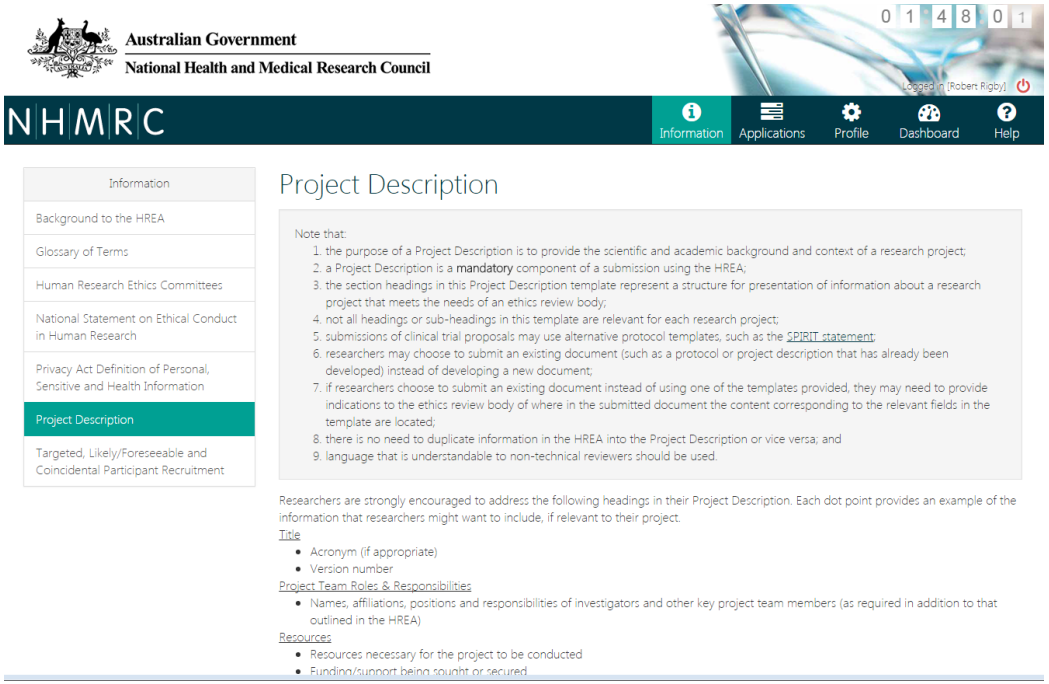
The HREA

- 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 HREA

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



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 superviser 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