Human Research Ethics
Information session

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"It doesn't matter that you never got caught!"
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(in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database being accessed.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!
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).


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
Complete your application on HERA
* Choose UQ as your institute

UQ Office of Research Ethics receives your application

Ethics officer does preliminary review of your application

Further information required => Ethics officer contacts you

You provide required information

Application is complete => Ethics officer forward application to the Committee for approval

LNR projects are reviewed by faculty sub-committees

Higher than LNR projects are reviewed by HREC

UQ Office of Research Ethics sends you the Committee's comments and decision
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:

• 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

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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).
Click on the “Application” button
You now see 3 vertical dots next to your application code.
Click on the 3 dots and a new window opens. Click on “invite user to register or share application”.

![Image of NHMRC website interface]
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.