HUMAN RESEARCH ETHICS IN AUSTRALIA

The *when*, *how*, & *by whom* of ethical review

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WHEN is ethical review required?

Australian Health Ethics Committee (NHMRC)

- AHEC is responsible for:
  - Advising on ethical issues related to health.
  - Issuing of human research guidelines.
  - Considering ethically significant issues relating to human health and research.

Human research guidelines

- National Statement on Ethical Conduct in Research (2007)
  - Ethical guidelines for researchers, HRECs, and organisations.
  - Developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.
  - Compliance is a prerequisite for receipt of NHMRC funding, other Government and competitive grant schemes.

What is human research?

- Human research is conducted with or about people, or their data or tissue.
  - taking part in surveys, interviews or focus groups;
  - undergoing psychological, physiological or medical testing or treatment;
  - being observed by researchers;
  - researchers having access to their personal documents or other materials;
  - the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
  - access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

When is ethical review needed?

- Ethical review can be undertaken at various levels according to degree of risk involved in the research.

- 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.

Assessment of risk

- Assessment of risks:
  - identifying any risks;
  - gauging probability and severity;
  - assessing the extent to which they can be minimised; determining whether they are justified by the potential benefits of the research;
  - and determining how they can be managed.

Degrees of risk

- Negligible risk – Inconvenience
  - Egs inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.
- Low risk – Discomfort
- Harm – All things greater than discomfort

Potential harms in research

- physical harms: including injury, illness, pain;
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, 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.

HOW much ethical review is required? (and BY WHOM)

Exempted from ethical review

- Research that carries only negligible risk may be exempted from ethical review.
- Involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

Non HREC ethical review

- For research that carries only low risk and does not target a ‘vulnerable’ population or area.
- The levels of ethical review may include:
  - review or assessment at departmental level by the head of department;
  - review or assessment by a departmental committee of peers (with or without external or independent members);
  - delegated review with reporting to an HREC; or
  - review by a subcommittee of an HREC

HREC review – Full review

- All research that involves more than low risk;
- Research on:
  - Interventions and therapies, including clinical and non-clinical trials, and innovations;
  - Human genetics; Human stem cells;
  - Women who are pregnant and the human foetus;
  - People highly dependent on medical care who may be unable to give consent;
  - People with a cognitive impairment, an intellectual disability, or a mental illness;
  - Aboriginal and Torres Strait Islander Peoples;
  - People who may be involved in illegal activities.

ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS OR AREAS

Areas of ethical concern

- Issues of consent:
  - Research involving people where capacity to give consent is limited or non-existent.
- Managing distress:
  - People who may be more-than-usually vulnerable to various forms of discomfort and stress.
- Risks of disclosure:
  - Vulnerability of participants and researchers because of discovery of participants' illegal activity, and legal implications of such discoveries.

Research with Aboriginal and Torres Strait Islander Peoples

- The cornerstone of an ethical research relationship with Aboriginal and Torres Strait Islander Peoples is respect for and valuing of cultural and language diversity.
- Research design and practice needs to recognize 6 core values:
  - Reciprocity
  - Respect
  - Equality
  - Responsibility
  - Survival and protection
  - Spirit and integrity

Quality Improvement (QI) Activities

- All QI that is conducted with or about people require **ethical consideration**.
- National Statement's four core values apply to QI:
  - Research merit & integrity; Justice; Beneficence; and Respect.
- HREC for QI activities that are not low or negligible risk.

Key resource

NHMRC Human Ethics

http://www.nhmrc.gov.au/health-ethics

- National Statement (2007)
- NEAF (National Ethics Application Form)
- Discussion of ethical issues