History of institutional human ethics

- Began post WWII, starting with the Nuremberg trials and the subsequent code of conduct (1946-47), Declaration of Helsinki and the subsequent guiding principles (1964).
- In Australia human ethics is governed by the NHMRC in Canberra, via AHEC (Australian Health Ethics Committee).
  - Initially created for medical research, was extended for all human research in 1999.
  - In 2007 and 2015 National Statement on Ethical Conduct in Human Research (NS) was developed by NHMRC, ARC & AVCC.
    - after extensive review process in medical and academic institutions
    - Includes specific sections - on participants e.g. children & young people, dependent & unequal relationships, cognitive impairment/intellectual disability, ATSI, and more...
Nuremberg Code

The **Nuremberg Code** is a set of research ethics principles for human experimentation created as a result of the Nuremberg trials at the end of the Second World War.

The code consists of ten points:

- Required is the voluntary, well-informed, understanding consent of the human subject in a full legal capacity.
- The experiment should aim at positive results for society that cannot be procured in some other way.
- It should be based on previous knowledge (e.g., an expectation derived from animal experiments) that justifies the experiment.
- The experiment should be set up in a way that avoids unnecessary physical and mental suffering and injuries, except, in experiments where the experimental physicians also serve as subjects.
- It should not be conducted when there is any reason to believe that it implies a risk of death or disabling injury.
- The risks of the experiment should be in proportion to (that is, not exceed) the expected humanitarian benefits.
- Preparations and facilities must be provided that adequately protect the subjects against the experiment's risks.
- The staff who conduct or take part in the experiment must be fully trained and scientifically qualified.
- The human subjects must be free to immediately quit the experiment at any point when they feel physically or mentally unable to go on.
- Likewise, the medical staff must stop the experiment at any point when they observe that continuation would be dangerous.
Declaration of Helsinki

- The Declaration of Helsinki is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA).
- It is widely regarded as the cornerstone document on human research ethics.
- The fundamental principle is respect for the individual, their right to self-determination and the right to make informed decisions regarding participation in research, both initially and during the course of the research.
National Statement (NS)

• Outlines the:
  • Values and principles of ethical conduct
  • Risk, benefit and consent
  • Ethical considerations in the design and development; the review and conduct of research; and of the participants
  • Processes for research governance and ethical review

• There is some acknowledgement ‘that the NS may not work with all types of research/disciplines’.

National Statement (NS) - Principles

• Ethical research is based on four guiding principles
  • Research Merit & Integrity
    • Integrity - search for knowledge, recognized principles of conduct, researcher capacity.
    • Research Merit - contribution to knowledge based on thorough study of prior literature etc.
  • Justice - who receives benefits, who bears the burdens
  • Respect for the individual, the group and the greater society
  • Beneficence – to maximise benefits and minimise harm
National Statement (NS) - Risk

• Potential for harm, discomfort or inconvenience – includes likelihood and severity
• Assessed by examining
  • Identify type of risk
  • Gauge probability & severity
  • Assess extent to which can be minimised
  • Determine if risk is justified
  • Determine how risks can be managed
  • Determine who benefits & who bears the burden of research – is it the individual, group, or the greater society
The University has 22 HEAGs embedded within the faculties, schools, and departments. Three HESCs assess Standard Risk applications. The Central Human Research Ethics Committee (CHREC) provides oversight and guidance.

Ethics Committees at the University of Melbourne
Human research ethics applications follow a process of submission through Themis, review by a Human Ethics Advisory Group (HEAG), followed by a review by a Human Ethics Sub-Committee (HESC) for Standard Risk projects.
Questions