What is research?

1. Use and collection of individual/group data from participants or their records

2. Therapeutic research conducted to provide direct benefits to participants

3. Non-therapeutic research – derive knowledge and may not be of direct benefit to participants – particularly relevant with animal research
**Historical context**

1947: Nuremberg Code – most important document in history of ethics

1948: UN Declaration of Human Rights

1964: Declaration of Helsinki – six updates

1966: Statement of Human Experimentation (NH&MRC)

1966: UN Covenant on economics, social and cultural rights – updated 1997

1999: National statement on ethical conduct in research involving humans – updated 2007
Current statements

National Health and Medical Research Council


National Statement on ethical Conduct in Human Research 2007

Vulnerable populations/specific groups

Indigenous people, children, dependent relationships, conducting research overseas
Why is ethics in research important?

- Demonstrates the values and beliefs of humanity;
- Respect for other living things (human or animal);
- The scientific community emphasises honesty and openness.
What is research character?

- Commitment to advancement of knowledge, the scientific method, pursuit and protection of truth
- Honesty
- Accountability to the academic community, participants, animals and community
- Adherence to national/international standards and codes of research practice
What is research character?

RESPECT

- For autonomy of animals, individuals and groups
- Regard for their welfare, rights, beliefs and customs
- Protection of people with diminished autonomy
- Avoiding harm and promoting well-being
  (pain, discomfort injury, adverse effects of drugs, anxiety, stress, guilt, embarrassment, loss of self esteem, discrimination, labelling, stigmatisation, costs to participants, income or revenue loss)
What is research character?

Scientific adequacy (Beneficence and Justice):

- Research justified in terms of knowledge benefits to community, translation of findings, contribution to community
- Efficacy of research design
- Expertise and appropriateness of researcher
- Burdens and benefits of research should be shared in a just and equitable manner
- Research legal as well as ethical
KEY ethical principles

- Principle of voluntary participation - human
- Informed consent
- Risk of harm (physical and/or psychological)
- Confidentiality
- Right to withdraw - humans
- Institutional Review Boards approve project
When is ethics approval required?

When conducting research on humans or animals

Minimal risk research or full ethics

Ethics approval must be done through established HREC – no data should be collected until approval is given.
HREC will determine approval for

- Research with significant impact (sensitive subject matter, potential for harm)
- Registration of RCTs with A&NZ Clinical Trial Registry – Declaration of Helsinki requirement
- Multi-institutional research
- Research being conducted with commercial sponsor
- Research with grant support
Informed consent

- Participants must be given clear descriptions of research and be fully informed of the extent of their participation
- Withdrawal rights
- Competent to give consent
- Data storage, access and destruction
- Ethical approval details
Confidentiality and privacy

➢ No individual identified from study data
➢ Safe storage of data
➢ Restricted access to data
➢ Destroying data
➢ De-identified and re-identified data
Approval questions for HRECs

- Will research provide new knowledge, benefits to community, translation, applied research?
- Is participant fully informed?
- What will they be required to do?
- How will adverse events if any be managed?
- Data storage and access
- What happens to participants at end of research?
Tips for completing ethics applications

- Allow time answer all questions, read form carefully,
- Provide all required documents, information and keep to word limits
- Proof read application

Helpful Tips
References


Zwar, N. *Research Ethics Workshop: A practical workshop on how to complete a human research ethics application* Fairfield Hospital, NSW