Human Research Ethics

What Do you Need To Know?

Barbara I Polus
The Role of the Human Research Ethics Committee (HREC)

- To protect the welfare and rights of participants in research involving humans, their data or their tissue
  - In order to achieve this, the HREC
    - Ensures that research proposals conform to the principles laid down in the *NH&MRC National Statement on Ethical Conduct in Research involving Humans, 2007*
    - Therefore, the RMIT HREC must be compliant with the 2007 National Statement
National Statement on Ethical Conduct in Research involving Humans (2007)

- Create an “ethos” for those who are engaged in human research to conduct their research in the “right spirit” – having an “…abiding respect and concern for our fellow creatures” (National Statement, 2007)
- Protect the rights and welfare of participants
- Inform the researcher of their responsibilities
- Inform the institution (university / hospital) about their legal obligations in approving, monitoring, recording and reporting research activities carried out within the university
Main Changes Between N.S. (1999) and N.S. (2007)

• Section 2.1 – definition of risk

• Section 3.1 – additional guidelines for different types of research – e.g. qualitative research

• Section 4 – guidelines on ethical considerations to specific groups

• Section 5.1 – guidelines on research governance and ethical review
RMIT Response to N.S. (2007)

- Disbanding the College sub-committees and replacing these with the College Human Ethics Advisory Network (CHEAN)

- What is the CHEAN?
  - A network of academics appointed by the PVC-A

- Role of CHEAN
  - To educate, advise and review negligible and low risk research from staff and students of the college
  - To facilitate and advise on the completion of the ethics application
  - To enhance increased awareness and understanding of ethical issues associated with the conduct of research involving Humans
  - CHEAN members are here to help you
RMIT Response to N.S. (2007)

• Increased efficiency of the ethics review process by;
  – Stream-lining the ethical review process
    – Adoption of new negligible / low risk application form which will include a checklist allowing the applicant to assess the level of risk associated with their research
  – Education of members of the College community about ethical issues associated with research involving humans – conducted by the CHEAN members
  – Alignment between research governance at RMIT and human research ethics
How Does the CHEAN Assess Ethical Implications of Proposed Research?

• In order to protect the welfare of research participants, the CHEAN needs to know:
  – **WHAT** the research is about; what is the researcher wanting to do?
  – **WHY** it is important / necessary to conduct the research
  – All research is associated with some level of risk / inconvenience to the participant
  – Does the **benefit outweigh the risk?**
How Does the CHEAN Assess Ethical Implications of Proposed Research?

• The CHEAN also needs to understand **HOW** the researcher intends to collect data
  – That is, what is the research method?
  – What is the researcher asking the participant to do?
  – The participant also needs to understand what is expected of her/him
  – Only then can the potential participant of the research give **informed consent**
Informed Consent

• Informed consent is the central ethical principle for conduct of research involving Humans

• It is founded on the doctrine of respect for the person and the principle of autonomy

• Autonomy (self determination)
  – The individual is the rightful determiner of her life and what should / can be done to her
Welfare of Research Participants

- Understanding the **WHAT, WHY and HOW** allows the ethics committee to determine the ethical issues associated with the research and to determine:
  - The level of RISK to participants
Risk levels

• The 2007 National Statement defines risk as;
  – “... a potential for harm, discomfort or inconvenience and involves:
    – The likelihood of harm (discomfort or inconvenience)
    – The severity of harm, should it occur, and its consequences”
  – See N.S. (2007) p. 16
Risk level - HARM

• May include (please see p. 16 of the N.S.);
  – Physical
  – Psychological
  – Devaluation of personal worth
  – Social harm
  – Economic harm
  – Legal harm
Risk level - DISCOMFORT

• Defined as less than HARM – and includes discomfort of body / mind

• Examples of discomfort might include
  – Discomforts relating to measurement of blood pressure
  – Anxiety induced by an interview

• Where a person’s reactions exceed discomfort and become distress, they should be viewed as harms
Risk level - Inconvenience

• Less serious than discomfort is inconvenience

• INCONVENIENCE – includes things such as giving up time, filling in an anonymous survey
Risks Can Also Extend to Non-Participants of the Research

- Risk of distress for a participant’s family member identified with a serious genetic disorder
- The possible effects of a biography on family or friends
- Infectious disease risk to a community
- Research in a small community into specific sub-populations may lead to unfair discrimination or have effects on social cohesion, property values or business investment
Application Review Process
What Does The CHEAN DO?

• Determine ethical issues associated with the proposed research
• Gauge the level of risk
• Ensure that all risks are minimised – how does the research design minimise risks?
• Do the benefits outweigh the risks?
• Managing the risks: does the proposal have;
  – Mechanisms to adequately deal with any harms that occur
• The HREC must have in place a monitoring process for approved applications
Take Home Messages

• All research conducted on Humans must involve careful thought to the possible role that Human participants may play in the research process

• The ethical review process is important and acts as a monitor / guide to protect the welfare and rights of participants in research involving Humans – but it is only part of the process

• It is the responsibility of all of us to ensure that all research conducted on Humans is *ethically acceptable*
The RMIT University Human Research Ethics Committee Home Page

The National Health and Medical Research Council Human Research Ethics Home Page