

Research Ethics: A New Zealand perspective



General ethical perspectives

- Ethics of consequences E.g. utilitarianism (ethic of consequences - a teleological ethic)
- Deontological ethics - Kantian Ethics - "Jim the explorer"
- Notion of moral agency/integrity
- Psychological research often makes utilitarian judgements

Points in the research process where ethical issues can arise

- Formulation of the research question
- Research questions have a "moral partiality"
- The framing of the research question affects what we find
- A fit with the prevailing social climate

Points in the research process where ethical issues can arise

- Conduct of research and treatment of participants
 - confidentiality of info
 - privacy needs of participants
 - sensitivity of the topic and nature of the research process

Points in the research process where ethical issues can arise

- Institutional context
- Power discrepancies

Points in the research process where ethical issues can arise

- Interpretation and application of the research findings
- Mainly application of findings for other than the original purpose e.g. use of IQ tests to develop a policy of sterilization for the mentally 'retarded'
- Powerful ideas can generate powerful policies
- The problems we address are often scientific, moral and practical problems

Basic Ethical Principles

- Respect for Persons
- Beneficence
- Social Justice

- See The Belmont Report 1979
- <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

Respect for Persons

- Fundamental Principles
 - All individuals should be treated as autonomous agents
 - Persons with diminished autonomy are entitled to increased protection

Respect for Persons

- Vulnerable Subjects
 - Prisoners
 - Children
 - Students
 - Subordinate
 - Decisionally impaired

Respect for Persons

- Informed Consent

A process or information exchange that takes place between the prospective subject and the investigator, before, during, and sometimes after the study

 - Information
 - Comprehension
 - Voluntariness

Respect for Persons

- **Information**
 - Purpose of research
 - Research procedures
 - Risks and anticipated benefits
 - Alternative treatments
 - Opportunity for questions
 - Withdrawal without penalty
- **Comprehension**
 - Organized presentation of research goals
 - Level of language
 - Time for consideration
 - Time for questions
 - Address impediments to understanding
 - Post-meeting 'quiz'
- **Voluntariness** - free of coercion or undue influence

Information and deception

- **Deception (active vs. passive)**
 - Active: when researcher lies about the purpose of the research
 - Passive: intentionally withholding information ...leaving out some information
 - NB: What probably matters ethically is the effect of the deception on the participant
 - Double deception: researcher (after the experiment) still tells participants a lie about the purpose of experiment

Information and deception

Incomplete disclosure

Only if truly necessary for the completion of the research

Only if undisclosed risks are no more than minimal

Only if debriefing, and results dissemination plan is in place

Distinction between disclosures that would invalidate the research versus disclosures that would inconvenience the researcher

Beneficence

General Principles

- Do no harm
- Maximize possible benefits and minimize risks.

Beneficence

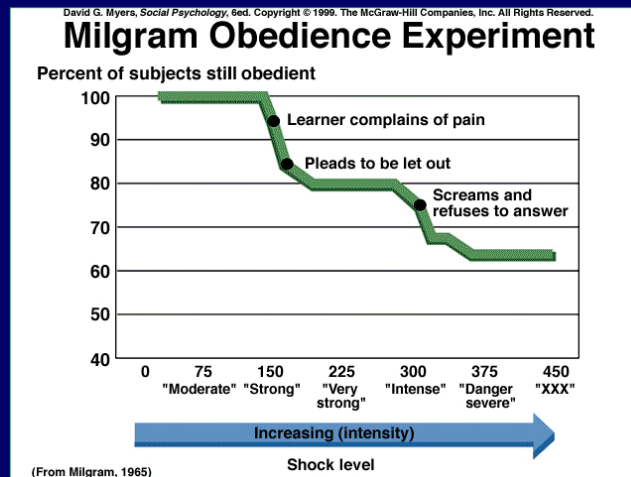
Assessment of Risk and Benefit

- **Risk**
 - Chance, or probability, that a harmful event might occur
 - Severity, or magnitude, of potential harm
- **Benefit**
 - Something of positive value related to health or welfare

Beneficence

- Must assess the balance between personal risk borne by the study participant and the potential societal benefit

The Milgram Study



- "In the first four conditions 71 of the 160 subjects showed definite signs of nervous laughter and smiling. The laughter seemed entirely out of place, even bizarre. Full-blown uncontrollable seizures were observed for 15 of these subjects. On one occasion we observed a seizure so violently convulsive that it was necessary to call a halt to the experiment" (Milgram, 1965, p. 68).

- I observed a mature and initially poised businessman enter the laboratory smiling and confident. Within 20 minutes he was reduced to a twitching, stuttering wreck, who was rapidly approaching a point of nervous collapse (Milgram, 1963, p. 377).

Milgram argued...

1. The harm was only temporary.
2. The subjects consented to or accepted the harm subsequently.
3. The harm was outweighed by benefits to the subjects.
4. The harm was outweighed by the importance of the knowledge generated.

Justice

- Fairness in distribution.
- Fair selection of study participants
 - availability or compromised position
 - groups unlikely to be among the beneficiaries of research findings

Justice

- Fairness of selection assessed at individual and societal level
 - **Individual level**
 - Inclusion and exclusion criteria
 - Specific consideration of women, children and minorities
 - **Societal level**
 - Selection should be based upon 1) ability to bear research burdens and 2) appropriateness of placing research demands on people/population

Long term consequences

- Who is responsible? - to what extent?

Boston Couples Study

231 couples fill out questionnaires once a year for a period of three years.

The questionnaire includes measures of sexual behaviour and attitudes, patterns of self disclosure, romantic love and liking, perceived power and decision making, perceived problems in the relationship, and thoughts about the future of the relationship and marriage.

At the end of the study, 20% of the couples had married, 35% were still dating or going out together, and 45% had broken up.

Half (47%) of the men and women thought that taking part in the study had at least a slight impact on their relationships.

A small proportion of respondents (4%) report that participation in the study caused their relationship to become "much less close".

One of the participants writes a letter to you as the researcher in which she states "I curse your study for destroying a lot of my fantasies about my boyfriend".

The Tuskegee Syphilis Experiment

- Between 1932 and 1972, the U.S. Public Health Service (PHS) - experiment on 399 black men in the late stages of syphilis.
- Men - illiterate sharecroppers from one of the poorest counties in Alabama - never told what disease they were suffering from or of its seriousness.
- Informed that they were being treated for "bad blood," (doctors had no intention of curing them of syphilis at all)
- Actively kept effective treatments (penicillin) from subjects - required vigorous efforts at deception at high levels
- *Penicillin - effective treatment (widely available after WWII), early treatments - heavy metals (mercury), arsenic based drugs*

The Tuskegee Syphilis Experiment - Why participate?

- The sharecroppers' grossly disadvantaged lot in life made them easy to manipulate
 - Free medical care - most had never seen a doctor
 - Free physical exams
 - Free rides to the clinic
 - Hot meals on exam days
 - Free treatment for minor ailments
 - Burial stipends
 - Nurse Eunice Rivers

The Tuskegee Syphilis Experiment

- Key ethical issues:
 - Deliberate non-treatment
 - under-treatment
 - deception
 - exploitation

The Tuskegee Syphilis Experiment

- Study spanned 40 years
 - By the end 28 men had died directly of syphilis, 100 were dead of related complications, 40 of their wives had been infected, and 19 of their children had been born with congenital syphilis.

The Tuskegee Syphilis Experiment: Ongoing legacy

- Widespread mistrust of researchers, Government, health system, and white people, among the African American community
- "...so many African-American people that I work with do not trust hospitals or any of the other community health care service providers because of that Tuskegee experiment. It is like...if they did it then they will do it again."

- Thomas, Stephen B. and Quinn, Sandra Crouse, "The Tuskegee Syphilis Study, 1932-1972: Implications for HIV Education and AIDS Risk Programs in the Black Community," Am J. of Pub Health. 1991; 81: 1503.

The Tuskegee Syphilis Experiment: Ongoing legacy

(1990 survey)

- 10% of African Americans believed that the U.S. government created AIDS as a plot to exterminate blacks
- 20% could not rule out the possibility that this might be true

Research Ethics at Massey University


Research Ethics at Massey University

- A single university-wide committee
 - Note: **Community Members**
Five or six members from the community
 - At least **two female** and **two male**,
 - **One Maori** who should have an awareness of te reo Maori and an understanding of tikanga Maori.
 - At least **one lawyer** and **one member should have expertise in ethics** (eg a teacher of ethics, philosopher, theologian, community recognised person such as a Maori elder)

Research Ethics at Massey University

- Ethical decision making heavily constrained by legislative obligations e.g.
 - Human Rights Act 1993
 - Privacy Act 1993
 - Health Information Privacy Code 1994
 - Public Records Act 2005
 - Copyright Act 1994
 - Education Act 1989
 - Injury Prevention, Rehabilitation, and Compensation Act 2001
 - Health and Safety in Employment Act 1992

Code of Ethical Conduct

 Massey University Te Kunenga ki Pūnehuru		
CODE OF ETHICAL CONDUCT FOR RESEARCH, TEACHING AND EVALUATIONS INVOLVING HUMAN PARTICIPANTS		
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3 types of application

- Full application
- Low risk notification
- Application to Health and Disability Ethics Committee
- Type of application decided by a Screening Questionnaire
- There are additional points we are required to consider

Consider Full application document....

Use of standardised templates

- Information Sheet
- Participant Consent Form
- Confidentiality Agreement
- Transcript Release Authority
- (see attached documents)

Low risk notification

Concluding comment

- Unethical research is bad research.
- In a well thought through system, consideration of issues of ethics should not be a bureaucratically-imposed burden, but an aspect of planning research that is central to good research.
- *Procedures/templates, pro-formas* should be well-designed to help researchers provide the information that the ethics committee requires.
- Clarity of language, avoidance of linguistic complexity, opacity, critical to a good application

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