



Towards principled ethics review

John Oates, Chair, Open University REC

overview



- Brief history of development of research ethics
- Research benefits, risks and constituencies
- Principles for researchers
- Principles for RECs
- A General Principle
- Discussion



A brief and highly selective history of the development of research ethics to identify the elaboration of issues and practices

1750 BC Hammurabi's code (Babylon)



- 113. If a physician make a large incision with an operating knife and cure it, or if he open a tumor (over the eye) with an operating knife, and saves the eye, he shall receive ten shekels in money.
- 115. If a physician make a large incision with the operating knife, and kill him, or open a tumor with the operating knife, and cut out the eye, his hands shall be cut off.

500 BC Hippocrates



I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion....

Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption ...

Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.

1833 Percival's code (England)



New methods of chirurgical treatment should be devised but, in the accomplishment of the salutary purpose, the gentlemen of the faculty should be scrupulously and conscientiously governed by sound reason, just analogy, or well-authenticated facts.

And no such trials should be instituted without a previous consultation of the physicians or surgeons according to the nature of the cause.

1833 Beaumont's code (USA)



- There must be recognition of an area where experimentation in man is needed.
- Some experimental studies in man are justifiable when the information cannot otherwise be obtained.
- The investigator must be conscientious and responsible ... for a well considered, methodological approach is required so that as much information as possible will be obtained whenever a human subject is used. No random studies are to be made.
- The voluntary consent of the subject is necessary.
- The experiment is to be discontinued when it causes distress to the subject.
- The project must be abandoned when the subject becomes dissatisfied.

1898 Walter Reed (USA)



First use of consent contracts to indicate informed consent. He wanted volunteers to know what sorts of risks they faced, that he would control the environment as best he could, that he would make medical assistance immediately available, and that in spite of this, they might die.

1931 The Reich circular (Germany)



- 5. Innovative therapy may be carried out only after the subject or his legal representative has unambiguously consented to the procedure in light of relevant information provided in advance. Where consent is refused, innovative therapy may be initiated only if it constitutes an urgent procedure to preserve life or prevent serious damage to health and prior consent could not be obtained under the circumstances.
- 7. Exploitation of social hardship in order to undertake innovative therapy is incompatible with the principles of medical ethics.



After WW2, in October 1946, the *Nuremberg Medical Trial* began, lasting until August of 1947. Twenty-three German physicians and scientists were accused of performing cruel and lethal medical experiments on concentration camp inmates and other living humans between 1933 and 1945.

Fifteen defendants were found guilty, and eight were acquitted. Of the 15, seven were executed and eight were imprisoned.

1947 The Nuremberg Code



The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

1947 The Nuremberg Code



- The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
- The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

1964 Declaration of Helsinki (Finland)



In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

1966-2008



- 1966 formation of first British REC
- 1978 British Psychological Society research ethics code
- 1991 Department of Health guidance for RECs
- 1999 Association of Research Ethics Committees
- 2000 Central Office for Research Ethics Committees
- 2001 European Union Directive 2001/20/EC
- 2004 UK Clinical Trials Regulations
- 2004 RESPECT framework - socio-economic research
- 2004 ESRC Research Ethics Framework
- 2007 National Research Ethics Service
- 2008 Integrated Research Application System (IRAS)



**Research risks and harms,
benefits and goods,
and constituencies**

Risks and harms



- physical trauma/injury?
- distress?
- offence?
- breach of confidentiality?
- inconvenience?
- coercion?
- waste of time?
- waste of resources / funds?
- disrepute or litigation?
- failure to publish?

Benefits and goods



- research as intrinsic good?
- contribution to knowledge?
- development of theories?
- improvements to lives?
- training researchers?
- career advancement?
- enhancing reputation/image?
- increasing commercial success?
- entertainment and enjoyment?

Proliferation of guidelines, regulations



- specific rules cannot cover all forms and topics of research
- there are always loopholes to be found
- over-regulation violates academic freedom and individual responsibility
- the need for training escalates
- researchers may opt out, avoid, evade if process too onerous

The BPS 'creed'



- 'Thinking is not optional'
- Researchers need to analyse risks and benefits, and develop fitting protocols
- The researcher retains agency in the process

Principles for researchers



- respect for the autonomy and dignity of the individual
- scientific value
- social responsibility
- maximise benefits and minimise harms

Principles for RECs



- independence
- competence
- facilitation
- accountability

A General Principle



- Proportionality
- Identify risks and benefits
- Tailor protocols and review processes accordingly
- Develop triage mechanisms
- Develop ongoing governance of projects in relation to risk levels



Discussion