

Ethics in Research

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Ethics: Definition

- A set of rules to play the game
- “Everyone playing the game must abide by the prevailing ethical standards. To the extent that a person or group does so, they are rated better or worse on the scale of ethical behaviour.

- D. Christianson

Conflicts of Interest

- Is everyone playing by the rules?

Conflict of Interest

- A conflict of interest exists when professional judgement concerning the well-being of a patient has a reasonable chance of being influenced by other interests of the provider. Disclosure of a conflict of interest is required in communications to patients, the public and colleagues.

Conflicts of Interest

- What is unethical behaviour?
- How would you handle these cases?

Who are you the agent of/advocate for?

- The patient
or
- The drug company
or
- The institution (University, NEI)
or
- Your own advancement

Questions to ask yourself during this presentation:

What is unethical?

What is professional?

How would you handle this situation?

Issues Raised Under the Code of Ethics

- Poor Study Design
- Small Patient Series
- Good Money for the Doctor
- Promotion of Products without contributing to real scientific inquiry

Research

- Must be scientifically sound
- If it is scientifically unsound it is automatically ethically unsound

Declaration of Helsinki

- World Medical Association - 1964
- Tokyo - 1975
- National Institute of Health
- British Medical Research Council

Medical Research Regulation

- Duty of researchers
- 1 to obtain consent of patient / healthy volunteer
- 2 moral and legal importance of individuals exercising control of what happens to their bodies

Accounts of Clinical practice

- Clinician with a new theory on treatment
- Medical or Surgical
- Should seek ethical committee approval
- Patients must be informed that they are part of an experiment

Consent

Informed



Informed Consent

- Not a blanket endorsement
- Exceptions
- Practical problems in obtaining consent
- Individual right to consent vs moral responsibility of health volunteers and patients to do so

Submit to Ethics Committee

- Submission is circulated to members
- Members review the paper
- Researcher is invited to present paper
- Members meet
- Researcher presents paper
- Members consider application

Approval process

- Approved without change
- Approved subject to minor modification

Approval With-held

- Unethical
- Unethical in its present format

Approval With-held

- Proposal scientifically unsound
- Methodology
- Statistics incorrect

- Patient information sheet
 - misleading
 - incomprehensible
- Consent form
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Commercial Relationships

- Clinical judgment must not be affected by benefit from professionally related commercial enterprises.

Conflict of Interest

- Professional judgment has a reasonable chance of being influenced by other interests of the provider.
- Requires disclosure to the patient

Disclosure

- What do you tell a patient?
- Assume what a “reasonable” person would want to know.
- Nature of the procedure and indications.
- Uncertainties inherent in medical intervention.
- Expected benefits, consequences, probabilities
- Possible risks, probabilities (can't be exhaustive)
- Reasonable alternatives including observation

Conduct of Research

- Adds new responsibilities to the doctors duties
- Honor an obligation to the scientific process, the scientific community and the future of medicine.

Summary

- Ethical dilemmas are common to medical practice
- Examine your own behaviour
- Act in your patients best interest