Ethics in Biomedical Engineering

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Ethics and morality

- "Ethics is the philosophical study of morality"
  - Examination of moral beliefs and behaviours
  - Study of right and wrong and good and evil
- Morality refers to a code of conduct put forward by society, or some other group, e.g. a religion, that is accepted by an individual for his/her own behaviour

1 Frize, M Ethics for Bioengineers, Morgan & Claypool, 2012

Ethical theories

- Kantianism (Kant, 1724-1804)
  - Categorical imperative – actions arise from a sense of duty; treat others as moral equals; do not use others for your own purposes
- Act Utilitarianism (Bentham, 1748-1832)
  - An act is good if it benefits someone and bad if it harms someone; an act is measured based on its impact
Ethical theories

- Rule Utilitarianism (Mill, 1806-1873)
  - Actions should lead to increased happiness; produce the greatest good for the greatest number of people
- Social Contract Theory (Locke, 1632-1704)
  - Personal rights – the right to life, individual liberty and human dignity; one cannot be deprived of rights except in accordance with principles of fundamental justice

Ethical theories

- Theory of justice (Rawls, 1921-2002)
  - Each person may claim an adequate number of rights – e.g. freedom of thought, freedom of speech, freedom of association, the right to safety…
  - Claims must be consistent with all others having the same basic rights and liberties
  - Social and economic inequalities must have most benefit for the most disadvantaged members of society

Codes of ethics

- Professional organizations or societies often have a code of ethics
  - Professional engineering associations – PEO
  - Professional societies – IEEE, ASME, BMES
- Other codes have been developed specifically for dealing with issues regarding the sanctity of human life and human rights
  - Hippocratic oath – obligations to patients
  - Nuremberg code – experimentation involving humans and the importance of voluntary consent
  - Declaration of Helsinki – research on human subjects and use of human tissue
The Biomedical Engineering Society Code of Ethics

- The BMES code of ethics is available at:

- Professional obligations
  - Use knowledge, skills, and abilities to enhance the public safety, health, and welfare
  - Strive to increase the competence, prestige, and honor of the biomedical engineering profession.

- Biomedical engineers in health care
  - Regard the rights of patients and act responsibly
  - Consider the larger consequences with regard to health care delivery

- Research obligations:
  - Comply with legal, ethical and other research guidelines; respect the rights of human and animal subjects, colleagues, the public and scientific community
  - Publish and/or present research results accurately and clearly

- Training obligations:
  - Train biomedical engineering students in proper professional conduct and in performing and communicating research
  - Do not allow inappropriate special interests to influence training

Experiments with human subjects

- When using human subjects in research, one must consider four basic concepts:
  - Beneficence – do good for the individual and all persons; benefits arising out of the research must outweigh potential harm
  - Non-maleficence – do no harm to the individual or other persons; balance the benefits against potential harm
  - Autonomy – the individual has the right to make his/her own decisions; the individual must be told all the information required to make an informed decision; withholding information removes the right to autonomy
Experiments with human subjects

- Basic concepts:
  - Justice – treat everyone fairly; insure that the risks and benefits are distributed equally among all concerned; this becomes an important consideration when resources are scarce

Ethics approval

- Experimentation involving human subjects, or the use of human material, requires ethics approval
- An application for ethics approval will include:
  - Background on the research project
  - Overall goal and objectives
  - Methodology
  - Selection criteria for participants; any exclusion criteria
  - The number of subjects to be recruited
  - The recruitment procedure
  - How subject anonymity or confidentiality will be insured
  - Security and future use of the data

Ethics approval application

- The application must include a letter of information and consent form, which will be provided to all subjects
  - The letter of information fully describes what the subject will be asked to do; any risks should be pointed out; it should indicate any compensation to be paid to the volunteer
  - The consent form is signed by the subject, indicating that she/he has been fully informed regarding the research study and experimental procedure and that she/he consents to participate in the procedure
Queen’s University Research Ethics Board

- Queen’s has two research ethics boards
  - The General Research Ethics Board (GREB) for non-health sciences related research
  - The Health Sciences Research Ethics Board (HSREB) for health-science research
  - Biomedical engineering research is considered by the HSREB

Ethics approval - procedure

1. Researcher prepares ethics application
2. Application is submitted to HSREB
3. HSREB will expedite (short review) or perform a full review depending on the level of risk
4. Researcher addresses any ethical concerns
5. Research receives ethics approval

The consent form

- HSREB has a Consent Form Aid, outlining the necessary sections of the consent form, available at:
- http://www.queensu.ca/or/researchethics/REB/consentformaid REB.pdf
An ethical question – the HeLa cell line

- Read the following two articles:
  - Henrietta Lacks' Immortal Cells
  - Tissue rights and ownership: is a cell line a research tool or a person?
  - http://www.stlr.org/2010/03/tissue-rights-and-ownership-is-a-cell-line-a-research-tool-or-a-person/
- Consider the ethical issues surrounding the use of the tissue sample

References


Biomedical Engineering Society, www.bmes.org

Queen’s University, Health Sciences Research Ethics Board, http://www.queensu.ca/ors/researchethics/REB.html