Informed Decision Making

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What is informed consent?

- The notion of informed consent in research stemmed from the need for people of diverse backgrounds and beliefs to exist together.

- Such need makes it necessary that interactions between persons should be clearly spelled out.

What is informed consent? (2)

- In former times, when doctors were revered, there was little need for written consent forms.
- This was because there was a bond of trust between the doctor and the patient which is mutually and implicitly agreed.

What is informed consent? (3)

- However, in the modern age, such a bond is disappearing, so there is a need for clearly written contracts.

- Moreover, the idea of respect for individual rights and autonomy also make the idea of written consent forms necessary.

What is informed consent? (4)

- In research on human subjects, human beings are treated as if they were instruments for knowledge.

What is informed consent? (5)

Hans Jonas: "[The] compensations of personhood are denied to the subjects of experimentation, who is acted upon for an extraneous end without being engaged in a real relation where he would be the counterpoint to the other or to circumstance. Mere "consent" (mostly amounting to no more than permission) does not right this reification. Only genuine authenticity of volunteering can possibly redeem the condition of "thinghood" to which the subject submits." (Quoted from H. Tristam-Engelhardt, *The Foundation of Bioethics,* p. 290.)

What is informed consent? (6)

- Jonas' argument shows that, to treat human subjects as if they were instruments, or 'things' to be acted upon is to violate the basic human nature.

- Immanuel Kant: 'Always treat human beings as ends, and never as means.'

What is informed consent? (7)

- This shows that patients or human subjects have the right to refuse treatment (with some exceptions) or to refuse to participate in research, especially if such research involves interventions into their bodies.

Aims of informed consent

- To respect individual rights, especially rights to integrity of bodies and rights to autonomy of decision making.

- To establish that the research is of a cooperative or participatory nature without resorting to presumed common backgrounds.

Aims of informed consent (2)

- This shows that individuals signing the consent form must be both *informed* about the nature of the research he or she is undertaking, and that his or her decision is *voluntary*.

Process of informed consent

- Merely signing the 'consent form' does not constitute informed consent.
- The participants must know enough of the nature of the research to be able to make a decision on their own.

Basic principles of informed consent

Autonomy

- The subject is an individual capable of making decisions and judgments on his or her own, and must be given the opportunities to do so.

Basic principles (2)

- Beneficence
  - The research must be shown clearly to provide benefits (or potential ones) to the subjects and to others. At least the research must not directly harm the subjects, and any potential dangers must be clearly spelled out to the subjects. "Maximize possible benefits and minimize possible harms."

Basic principles (3)

- Justice
  - When selecting potential participants, care must be taken to ensure justice. Are the participants selected because of some preferential favor? Or is another group selected because the research carries more than minimal risks so this group is targeted for the possible risks?

What information is required?

- A statement that the study involves research.
- An explanation of the research.
- The purposes of the research.
- The expected duration of the subject's participation.
- Identification of any procedures which are experimental.

What is required? (2)

- A description of any reasonably foreseeable risks or discomforts to the subject.

- A description of any benefits to the subject or to others which may reasonably be expected from the research.

What is required? (3)

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

What is required? (4)

- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

What is required? (5)

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects's rights, and whom to contact in the event of a research-related injury to the subject.

What is required? (6)

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Cases where full informed consent cannot be obtained.

- In research involving individuals who cannot think for themselves, the decision of guardians who can act for them must be obtained.
- For example, children and demented patients.
- Who are the guardians or the legal representative?

Cross-cultural issues

- The idea of informed consent is rather new in Thai society.

- The idea came together with the advent of modernity.

- In former times, society was held by common beliefs and backgrounds.

Cross-cultural issues (2)

- However, when society becomes more complex, bonds between individuals begin to loosen, creating a need for a *secular* ethics.

Cross-cultural issues (3)

- One area that ethicists should concern themselves is how to adopt Buddhism to current practices of bioethics.

- Buddhism alone does not specifically mention informed consent, so a system of interpretation is needed.

Cross-cultural issues (4)

- Thai society is still deeply hierarchical. This creates a special need for taking an effort to ensure justice and informed consent.
- A possible scenario: A research using his ‘superior’ status in society to bring less privileged people to participate in his research.

Cross-cultural issues (5)

- Since the notion of informed consent is still rather alien to people in the rural areas, the researcher should take special care to remedy the situation.

- Consent forms may need to be explained, and read aloud if necessary.