

Informed Consent

Hemantha Senanayake

Chairman,

Research Ethics Committee,

Faculty of Medicine, University of Colombo

The Nuremberg Code

“the voluntary consent
of the human subject
is absolutely essential”

Later guidelines
i.e Helsinki, CIOMS
reassert
the primacy
of informed consent

Informed Consent

- An effort to uphold respect for the individual

Informed Consent

- Many people (wrongly) believe informed consent makes clinical research ethical
- Not sufficient – one of many components
- In some instances not necessary

Components of Informed Consent

- Information
- Understanding
- Voluntariness
- Decision making capacity

Components of Informed Consent *Information*

- The best way is to design consent forms and other information materials to a “*reasonable person standard*”
- Supplement with conversations

Components of Informed Consent

Types of information

- Nature and purposes of experiment
- Procedures involved
- Foreseeable risks and benefits
- Alternatives to participating in the research
- Protection of confidentiality
- Reassurance about leaving the study without forfeiture of care



DON'T FORGET!

The Tamil information sheet/consent form

Components of Informed Consent

Understanding

- A level of appreciation that is adequate for a meaningful deliberation about the decision
- The decision must reflect what the participant **intends to authorize**
- Informational material must be written at an appropriate level
- Test the subject's comprehension

Components of Informed Consent

Voluntariness

Authorization that is

- Given freely
- Representing one's own will
- Not another's
- Not controlled by anyone other than the participant

Components of Informed Consent

Voluntariness

- Consent obtained by fraud, deception or coercion is invalid

Special situations:

- Very ill cancer patients
- Teacher & student
- Poor patients infected with HIV
- Doctor & patient
- Refugees

Components of Informed Consent

Decision Making Capacity

- Needs a certain level of maturity
- Vulnerable populations (e.g. prisons, some healthcare facilities, certain relationships)
- Proxy consent in people who have lost or never developed decision making capacity

Informed Consent in “Unethical” Research

- Malignant melanoma cells were transplanted from her daughter to her “volunteering and informed” mother
- In the hope of gaining a better understanding of cancer immunity
- Also hoping the tumour antibodies might help in the treatment of the patient
- Patient was in critical condition and died the day after

From: Beecher HK, New Engl J Med, 1996

Informed Consent in “Unethical” Research

- Primary implant in the mother was widely excised on the 24th day after placement
- She died on day 451st day, of widespread melanoma

Is informed consent *always*
necessary?

Informed Consent *May* Not be required

- In investigations that do not directly involve human subjects – e.g. Audits
- Use of data that is publicly available
- No personally identifiable data
- Written consent may pose a risk to the individual – studies on recreational drug use, sexual deviations

Informed Consent in Special Situations

Informed Consent in Research on Children

Children

- Legally and (often) developmentally incapable of granting valid consent
- Guidelines have sought to protect children
- Primarily by restricting the level of research risk
- Parents as decision makers
- Assent of the child

Assent

- Sought in children over 8 years old
- Depends on the complexity of the research and.....
- Individual variations of the child's development
- ERC must consider the balance
- Dissent must be honoured

Research in pregnant women

Pregnant women

- In the socio-cultural context of Sri Lanka should the husband be asked?
- Concerns regarding potential for creating abnormalities

People with Cognitive impairments

Cognitive impairments

- Consent from 'legally authorized' person
- Close relative or guardian
- Depression –
essentially a mood disorder
would understand the risks
but not care about the risks?

Captive Populations



Captive Populations

- Internally displaced persons
- Soldiers
- Prisoners
- Students

Captive Populations

- Choices may be less than voluntary
- Situation may compromise their ability to give informed voluntary consent
- Justice in selection of participants may be affected

Medical Students

- Data from West show they do not feel coerced
- Autonomous, smart
- Many be the ideal research participant
 - Understands information
 - May get an educational benefit
- Special protections have been described as ‘overprotective paternalism’

Medical Students

Would this be true of Sri Lankan Medical students?