National university Sudan

Faculty of Medical Laboratory Sciences

Introduction to Research – MLS – RESH -326

Research Ethics

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Lecture (19)

Contents

What's Research Ethics ?

It is the field of ethics that systematically analyze the ethical (and legal?) questions raised by research involving human subjects.

- Its main focus is to ensure that the study participants are protected .
- Ultimately that clinical research is conducted in a way that serves the needs of such participants and of society as a whole..

History of Research Ethics

History

◎ **Before 20th century**

- Small scale, involving few individuals

◎ **Beginning of 20th century**

- Larger scale clinical trials
- Collect systematic data
- Groups of individuals
- Vulnerable groups (Prisoners ,Orphans , Mentally ill)

No Formal Codes of Research Ethics.

◎ Tuskegee Syphilis Study (1932 - 1972)

◎ Nuremburg Nazi Doctors' Trial (1947)

- Nazi doctors and Scientists put on trial for the murder of concentration camp inmates who were used as research subjects.
- Ushered in a new era in research ethics.

Guiding Documents

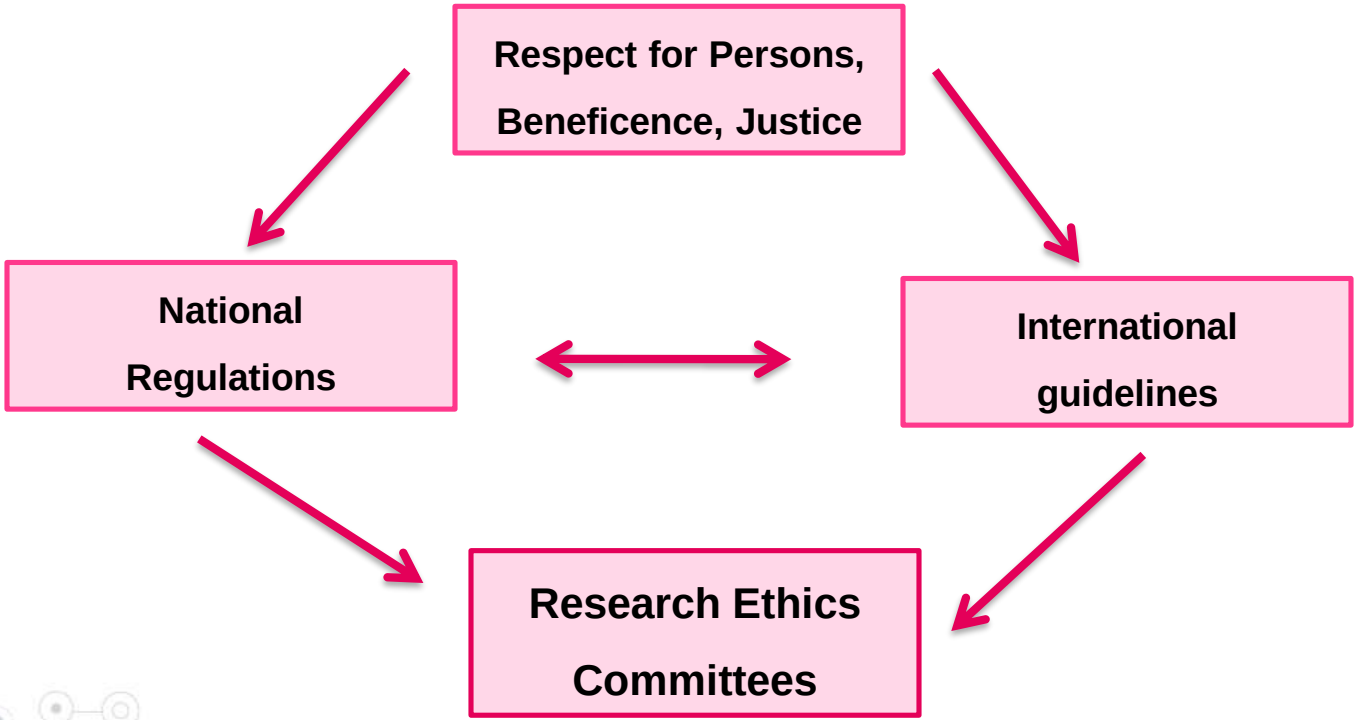
- Nuremberg Code.
- Declaration of Helsinki.
- Belmont Report.
- CIOMS Guidelines 2002.
- WHO Guidelines.
- In Sudan – local Sudanese guidelines.

Nuremberg Code (1947)

- First Codification of Research Guidelines
- Human Rights + Welfare of Subjects.
- The first and longest principle:

  The voluntary consent of the human subject is absolutely essential.
- Article (9): Subjects have the right to withdraw at any time.

From Fundamental Ethical Principles to Local Guidelines



The Principles of Research Ethics

Respect for persons

The right to make a decision

- Treat individuals as autonomous agents
- Protection for those with diminished autonomy.
- **Practical application in protocol review:**

- Informed consent.
- Surrogate consent for incompetent individuals.
- Privacy & confidentiality.
- Community partnership.

Beneficence

Corollary: Non-maleficence

- Maximize benefits & minimize risk of harm

Practical application in protocol review:

- Identify risks/minimize risks.
- Optimal study design: use least harmful methods to achieve scientific end.
- Favorable risk-benefit calculation.
- Social value/community partnership
- Ongoing safety monitoring.

Justice

Treat individuals fairly

- Practical application for protocol review:

◎ Selection of subjects

- Equitable distribution of research harms and benefits
- Equitable selection of subjects/participants within a population
- Equitable selection of population

◎ Recruitment practices

What Makes Scientific Research Ethical?
Guidelines for Research Ethics

- Social and Scientific Values
- Scientific Validity
- Fair Subject Selection
- Favorable Risk-Benefit Ratio
- Informed Consent
- Respect for Enrolled Subjects
- Independent Review
- Community Perspective

Social Value

To be ethical scientific research must lead to improvements in science or advancement in generalizable knowledge.

Research without value includes:

- Substantial overlap with prior studies
- Intervention can never be implemented
- Unimportant hypothesis

Scientific Validity

Research must be conducted with an appropriate methodology to ensure that the results will answer the original research questions.

Invalid research:

◎ Studies with inappropriate endpoints or statistical tests.

◎ Studies that cannot enroll sufficient subjects.

Favorable Risk-Benefit Analysis

- Risks are identified.
- Risks are minimized.
- Potential benefits enhanced.
- Risks are reasonable to potential benefits to subject and society.

Risks Minimized

- Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

Fair Selection of Subjects

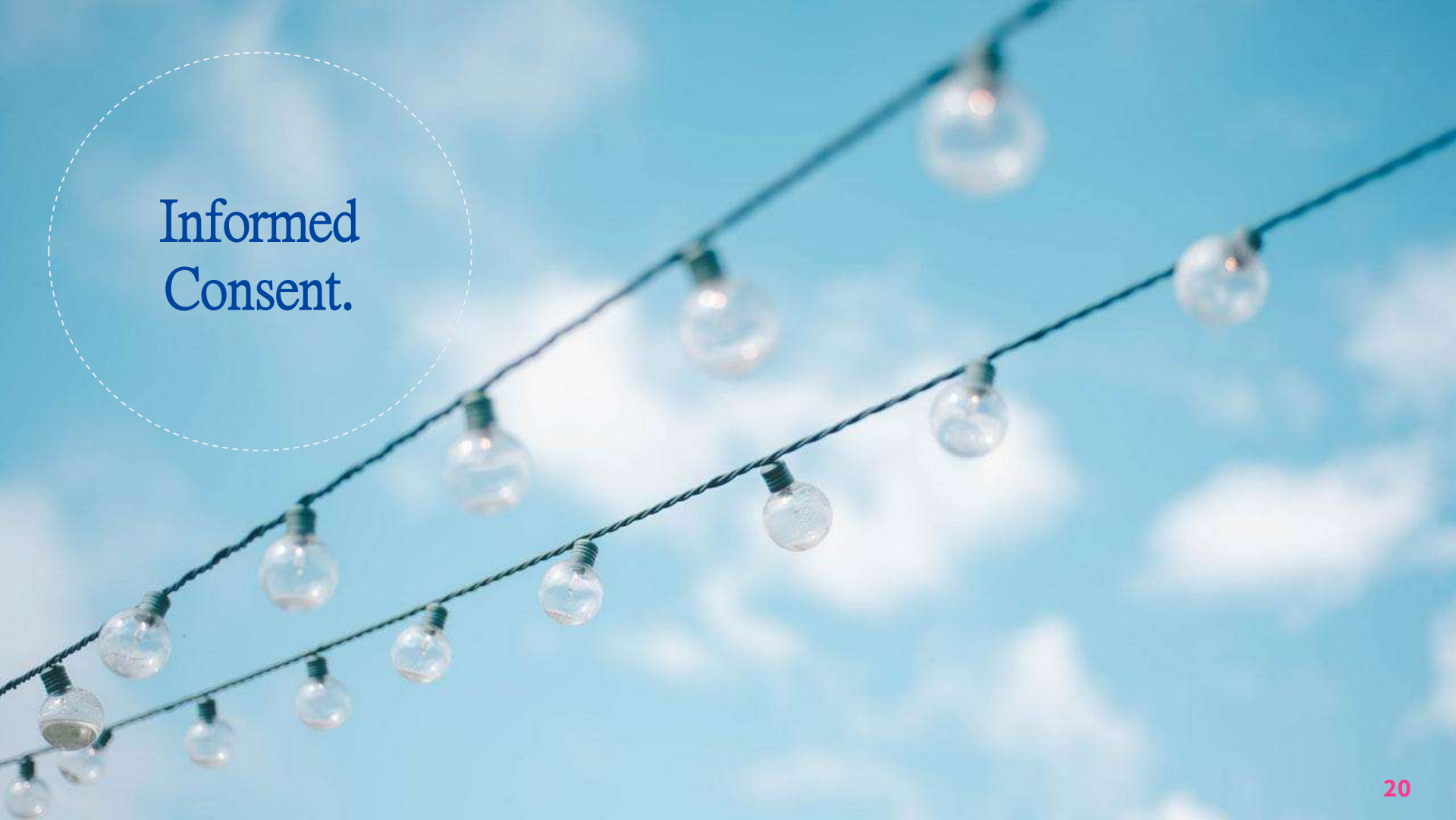
Selection of subjects is equitable

- Convenient (vulnerable) groups should not be targeted.
- Higher risk is a reason to exclude certain groups.
- **Research Ethics Committee should take into account:**

– Purposes of the research

– Setting of the research

– Special problems of individuals vulnerable to coercion or undue influence.


Informed
Consent.

Informed Consent

Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

Informed consent ensures that individual themselves decide:

- Whether to enroll in research
- Whether research fits with their own values interests, and goals.
- Research on individuals who cannot decide requires surrogate consent (Children and mentally impaired.)

Informed Consent requirement

- Disclosure of Information
- Comprehension .
- Decision Making Ability.
- Voluntariness.

Inducement

◎ Inducements are offers that get people to do things they would not otherwise do.

◎ Inducements in research:

- any activity to encourage participation
- payment or the offer of free medical care for research participation is not coercive.

Independent review

- Research Ethics Committee (REC)
- Institutional Review Board (IRB)
- ". . .contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants"

Research Ethics Committee (REC)

An ethical committee formally designated to review and approve the initiation of a clinical research study involving human participants and to provide continuing review of the research study .

Steps (REC)

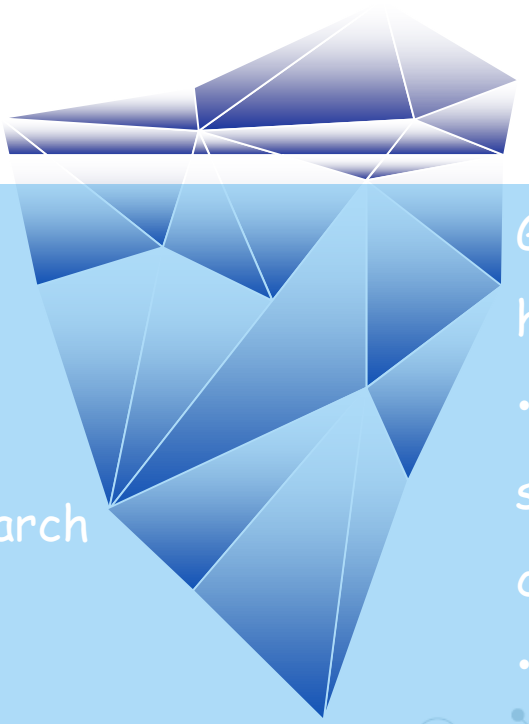
Develop Standard Operating Procedures

- Enhance
- Transparency
- Consistency
- Efficiency

Institutional Review Board

IRB decides reviewing depending on:

- Is it Research
- Is it Human Subject Research
- Level of Risk



Greater than minimal risk to high

- Controversial and complex study: stem cell, phase I clinical trial.
- Vulnerable participants.

Need Full Board reviewing

Research Misconduct

Scientific misconduct is defined as follows:

- **Fabrication**: is making up data or results and recording or reporting them.
- **Falsification**: is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Research Misconduct

- **Plagiarism**: is the appropriation of another person's ideas, processes, results, or words without giving appropriate record (reference).
- Honest errors or differing interpretation are not scientific misconduct.

Factors leading to misconduct

- Societal & cultural acceptance of deviant behaviour.
- Pressure to produce.
- Pressure for fame.
- Poor training.
- Education the scientific method.
- Poor education in ethics.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Thank You