Informed Consent

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Objectives

- To describe the reasons why research subjects may choose to participate in research
- To define what is meant by an informed consent (IC)
- To demonstrate how consent has been addressed in Ethics guidelines
- To describe the process of obtaining a valid IC
- To explain the elements (essential and additional) of IC
- To describe conditions where there could be a waiver of the IC

Why do research subject participate in research?

- Humanity/ Altruism
- Free medications and medical care
- Hope for new powerful treatment
- Attention (close to doctors & known expertise)
- Self-interest to advance science
- Monetary incentive

Informed Consent

- A process by which a study participant voluntarily confirms his or her willingness to participate in a particular research, after having been informed of all aspects of the research that are relevant to the study participant's decision to participate.

- Informed consent is documented by means of a written, signed, and dated informed consent form.

Informed consent

- IC is considered as requirement of ethical conduct in all major ethical guidelines.
- So how was it addressed in those guidelines?

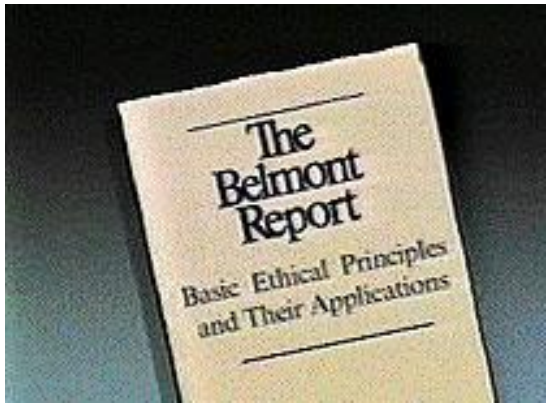
Nuremberg code

- First statement in the code:

"The voluntary consent of the human subject is absolutely essential."

Belmont report

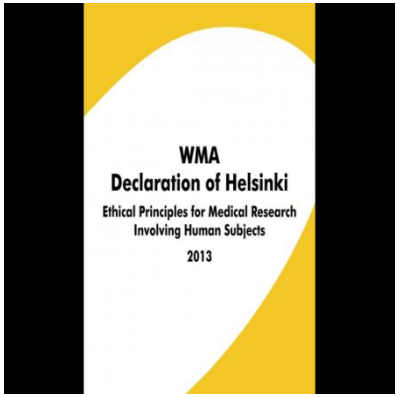
"Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."



Declaration of Helsinki

"Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees"

Helsinki 2013



CIOMS guidelines

"Researchers have a duty to provide potential research participants with the information and the opportunity to give their free and informed consent to participate in research, or to decline to do so, unless a research ethics committee has approved a waiver or modification of informed consent. Informed consent should be understood as a process, and participants have a right to withdraw at any point in the study without retribution ."

CIOMS 2016

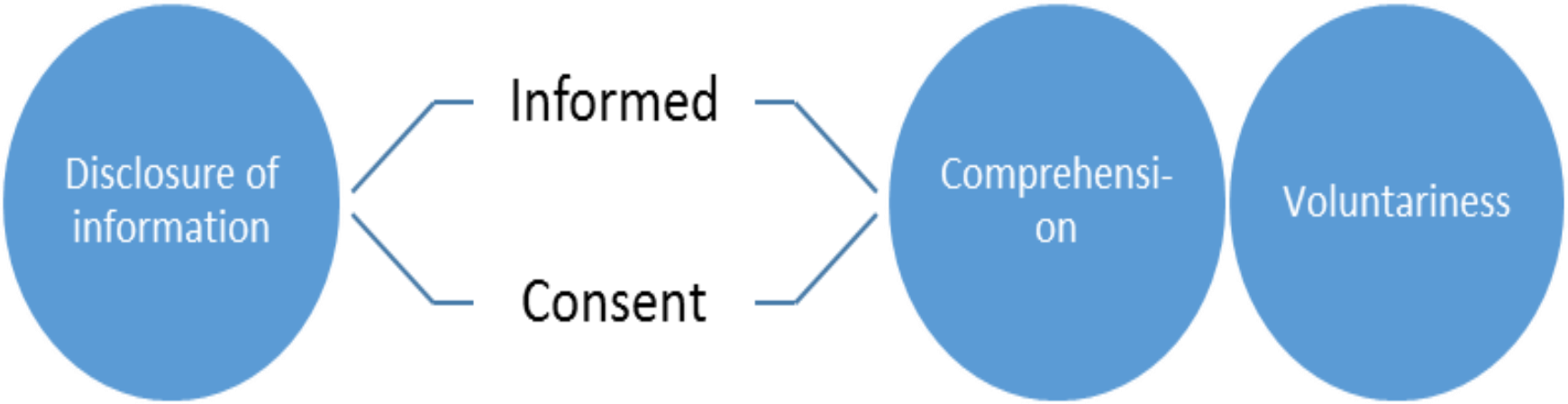
National guidelines

"The Informed consent reflects the ethical principal of respect to persons and their autonomous decisions. Enrolling individuals in research studies without their authorization is to treat them merely as a means to an end that they might not even agree with."

(Sudan Guidelines for Ethical Conduct of Research Involving Human Subjects ,2017)

Obtaining a valid consent

- Disclosure of information
- Decision making capacity /comprehension
- Voluntariness



Sudan Guidelines for Ethical Conduct of Research Involving Human Subjects, 2017

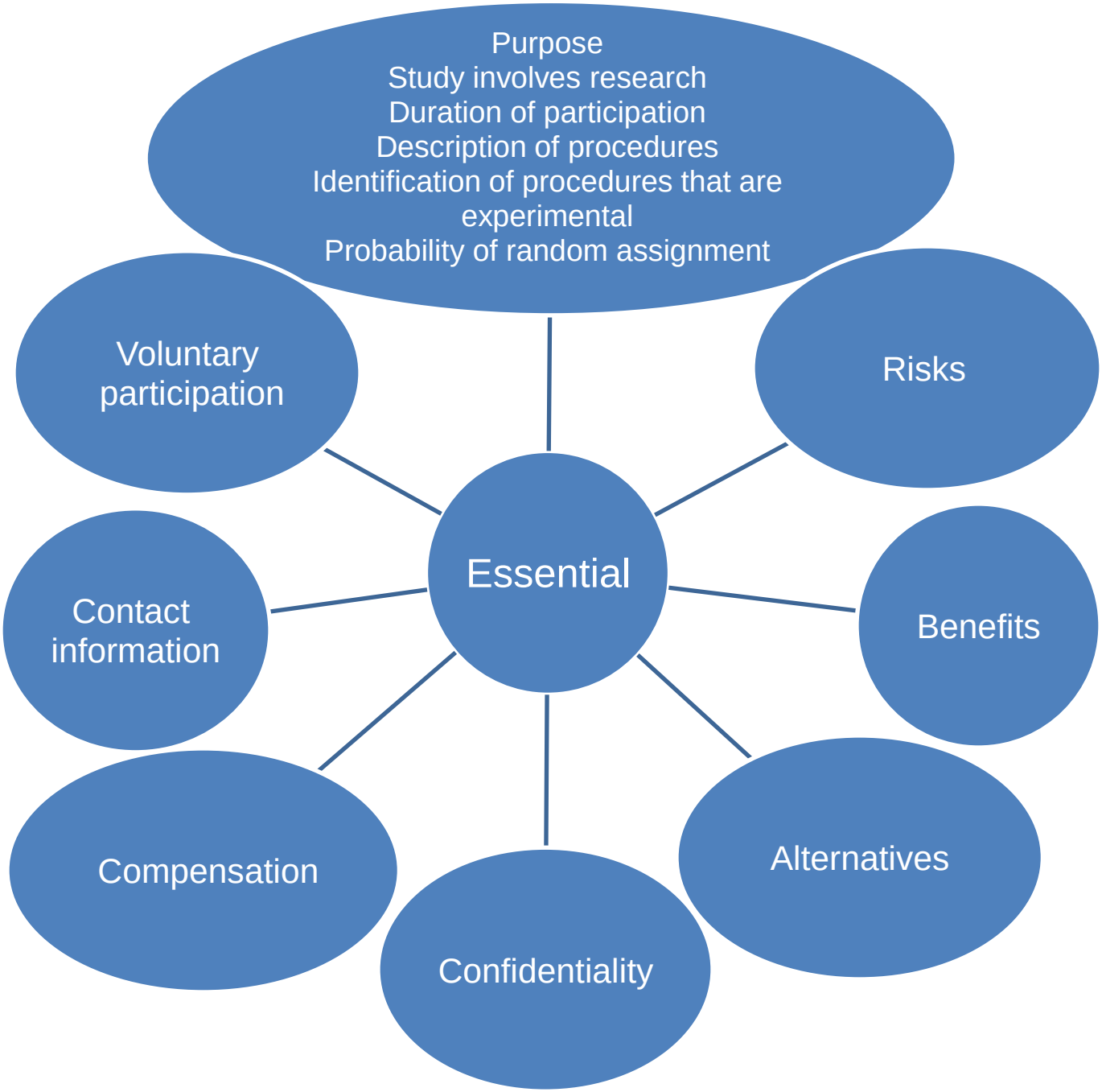
Disclosure of information

1. Essential Elements

The basic information that must be covered in any informed consent process.

2. Additional Elements

Information that need to be given to potential subjects when appropriate, this is dependent on the characteristics of the study and needs of the study population.


Purpose
Study involves research
Duration of participation
Description of procedures
Identification of procedures that are experimental
Probability of random assignment
Voluntary participation
Risks
Essential
Contact information
Benefits
Compensation
Alternatives
Confidentiality

1. Purpose of Research

- A statement that the study involves research
- An explanation of the purposes of the research
- Expected duration of the subject's participation
- A description of the procedures to be followed
- Probability of random assignment to each treatment
- Identification of any procedures that are experimental

2. Risks and Benefits

- A description of any reasonably foreseeable risks or discomforts to the subject
- The reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant
- A description of any benefits to the subject or to others which may reasonably be expected from the research

3. Alternatives

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

6. Research Questions

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

- Phone numbers
- Email

4. Confidentiality

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- Inspection of other agencies might inspect the records
- If the results of the trial are published, the study participant's identity will remain confidential

5. Compensation for Injury:

Research involving more than minimal risk:

- Explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs (if so what they consist of, or where further information may be obtained)
- The compensation and/or treatment available to the subject in the event of trial-related injury
- The anticipated payment, if any, to the study participant for participating in the trial

7. Voluntary Participation

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


Termination of subject participation
Incentives
Unforeseeable Risks
Additional
Number of subjects
Consequences of withdrawal
Anticipated expenses
New findings for consent

Additional Elements of Informed Consent

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
2. Anticipated circumstances to terminate subject's participation by the investigator without regard to the subject's consent

Additional Elements of Informed Consent

3. Incentives that research subject receives for participation in the study
4. The anticipated expenses, if any, to the study participant for participating in the trial.
5. Consequences of a subject's decision to withdraw from the research and procedures for orderly termination

Additional Elements of Informed Consent

6. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject
7. The approximate number of subjects involved in the study

Comprehension

- Informed consent is NOT a document, and giving a potential subject the document alone does not constitute a consent
- Informed Consent Forms must be written using lay terms in a language level understandable to all participants being consented and must include all basic elements and additional elements as appropriate

- Obtaining informed consent need to use the appropriate evidence based methods to explain the research to the potential subjects (these may include information leaflets and/or audio-visual aids to supplement written material)

- Factors including, literacy level, culture, beliefs, maturity, the ability of the researcher to communicate effectively and their competence in obtaining informed consent may all influence degree of comprehension.

Voluntariness

- For an Informed consent to be voluntary the potential subject needs to make their decision to participate in the research study without coercion, intimidation or undue inducement.
- Voluntariness can be jeopardized in different circumstances where potential subjects are deemed vulnerable.

Signature

Signature of the following people:

- Research Participant that they approve to participate in the study
- Principal investigator or authorized person
- Witness

Waiver of consent

Research should not be initiated in humans without obtaining the individual's informed consent or that of a legally authorized representative, unless a Research Ethical Committee approved otherwise.

Conditions of Waiver

- The research would not be feasible or practicable to carry out without the waiver or modification;
- The research has important social value; and
- The research poses no more than minimal risks to participants.

Waiver of signature

- Research studies which may carry an increased risk of harm if a breach to confidentiality occurs, RECs may approve waiver of documentation if the research subject does not want their identities linked with the study as the only record linking the subject to the research is the informed consent document e.g. research with intravenous drug users.

- If the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context.

Readings

- CIOMS guidelines 2016
- Declaration of Helsinki 2013
- Belmont Report 1989
- Guidelines for Ethical Conduct of Research Involving Human Subjects, second edition, Sudan 2017

Thank You