Introduction to Informed Consent in Clinical Trial

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By

Umobi C.P

RN, RM RPHN, RNE, BSc, MSc. Nsg

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Introduction

- Informed consent according to Oxford dictionary is consent to an action by another person given based upon a clear appreciation and understanding of the facts, implications and consequences of the action.
- In Medical purposes the term informed consent means permission granted in the knowledge of possible consequences (Selinger C.P 2009).
- Informed consent process is the fundamental of ethics in clinical research which is based on the moral and legal premise of patient autonomy

Introduction contd

It is a process where the subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate (International Council for Harmonization Good Clinical Practice guidelines, 2016).

Clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions (Manti et al, 2018). .

. Obtaining informed consent from the subjects is an important legal and ethical imperative for clinical trial researchers.

Introduction contd

- In clinical trial, the subject may be exposed to risks of the drug or treatment that are not known at the time of the study hence the very need for informed consent.

- Four key basic principles for the protection of participants of clinical research are justice, beneficence, non-maleficence and respect for autonomy.
- **Beneficence:** is the obligation to act for the benefit of the patient to protect and prevent harm, remove conditions that will cause harm
- Nonmaleficence: is the obligation of not to harm

Ethical Principle Contd.

Autonomy

- an ethical principle, concerned with the power of patients/subjects to make rational decisions and moral choices, and be allowed to exercise the capacity for self-determination
- **Justice**
- Justice is generally interpreted as fair, equitable, and appropriate treatment of persons.

Objectives of the presentation

1. To highlight the content of informed form
2. To describe the Elements of informed consent
3. To describe the process of obtaining informed consent in clinical trials.
4. To discuss special considerations in informed consent.

Brief History

- Ethical research practices arose after the infamous cases of the Nazi's experiments on concentration camp prisoners during the war II. There was sale of unlicensed drug Thalidomide to pregnant women and the Tuskegee Syphilis Study (1932 –1972) on black American men.

The misconduct that took place included:

- not being told everything about their diseases.
- being bribed with incentives they could not possibly refuse
- being kept in ignorant that their diseases can be treated.
- receiving insufficiently tested drugs
- being included in research that was life-threatening
- not being asked for their consent to be included in research
- being subjected to procedures which had no justifiable scientific or medical purposes

Development of Regulations and Guidelines

- In response to the cases cited above and the problems afterwards, guidelines for the conduct of clinical research were developed. These include the 1996 International Conference on Harmonization Principles of Good Clinical Practice (ICH GCP) Guidelines, the 2002 Council for International Organizations of Medical Sciences.
- They developed rules to observe when carrying out clinical research of which obtaining informed consent is a key rule.

Content of Informed Consent

- Informed Consent will express clearly that it is a research study and explain the purpose of the research.
- It must contain the anticipated duration of the subjects participation.
- A detailed account of any procedures or experimental procedures the participant must complete over the course of the trial.
- It must explain any potential risks involved with the trial.
- Any discomforts the participant may experience must be disclosed, such as injections.
- Expected benefits from research and information on alternative options that could also benefit the participant

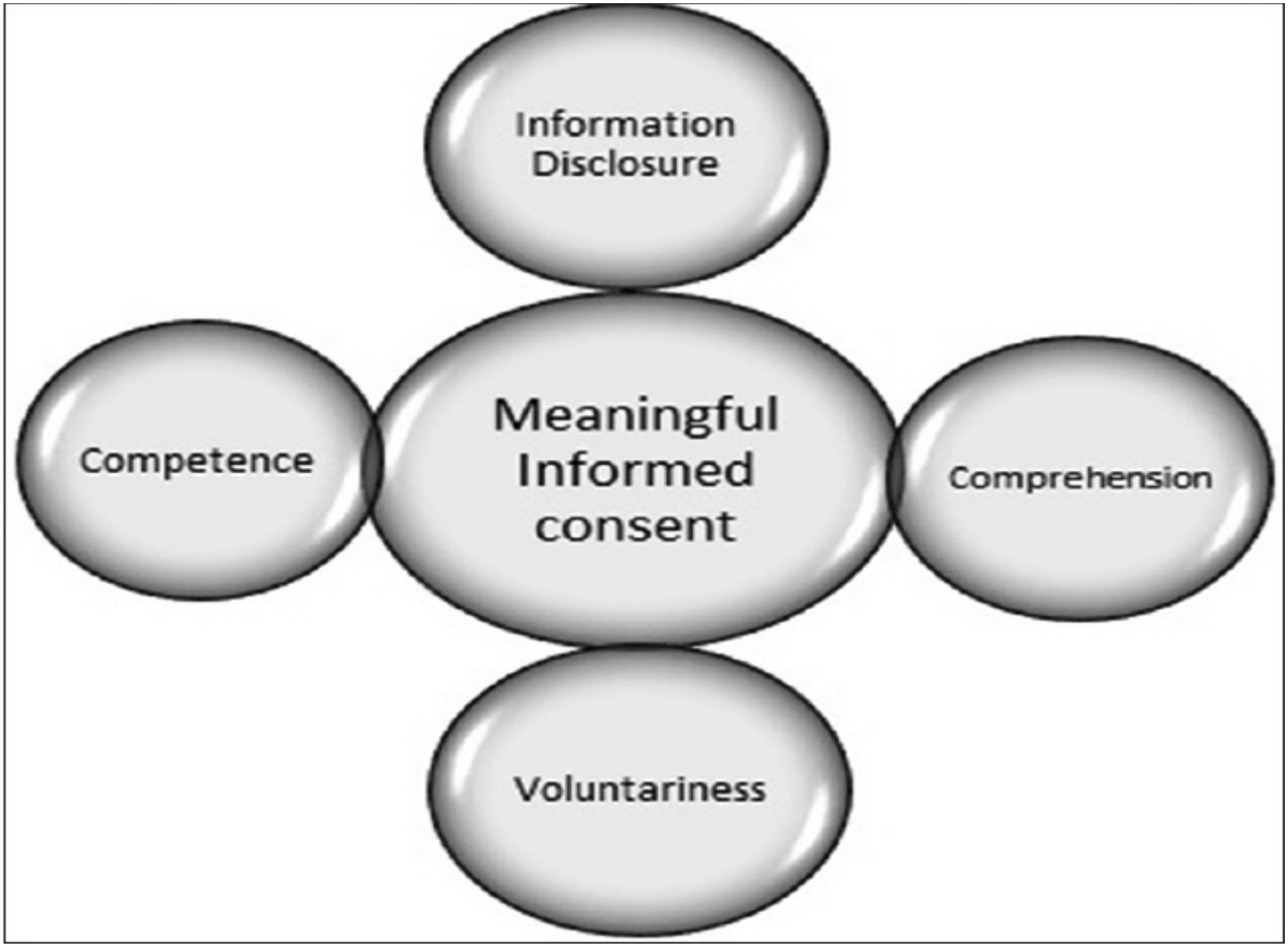
Content of informed consent contd.

- Any medical treatments or compensation that can be are provided in the event of injury, what they consist of.
- A statement listing the rights of the research participant.
- Subject must be informed that there may be unexpected risks involved with the study.
- Reasons that the participant may be removed from the study by the clinical trial investigator, such as failing to comply with procedures.

Content contd.

- Any costs the subject might expect to forego as a result of participating in the study.
- What will happen if the participant leaves the study before completing it.
- A statement that the participant will be informed of any important findings the study yields.
- The anticipated number of subjects to be enrolled in the trial.
- A statement of confidentiality regarding the data gathered from the study.
- Subject must be made aware that their records may be inspected by the Food and Drug Agency.
- Contact information for any questions and concerns about the study must be provided.

Elements of informed consent



Competence.

- Competency is a legal term used to indicate that a person has the ability to make and be held accountable for their decisions.
- It is the subject’s capacity or competence to understand trial information.
- Factors such as age, disease severity, cognitive disability, especially in elderly patients, and those with mental disorders may affect a subject's decisional capacity.
- The components of decision-making capacity are:
- ability to understand the options,
- ability to understand the consequences of choosing each of the options,
- ability to evaluate the personal cost and benefit of each of the consequences and relate them to own set of values and priorities

Disclosure

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- In order for you to give your informed consent in clinical trial, the researcher must give you enough information so that you, the research subject can make an informed decision.
- information on what would be expected by a reasonable person to make an intelligent decision.
- what will be done to them,
- How, the protocol (plan of research) works,
- what risks or discomforts they may experience,
- participation being a voluntary decision on their part.

Comprehension

- You must comprehend the relevant information. Information on the purposes of the research and the expected duration of the subject's participation, a description of the procedures
- The risks that will be involved with the study.
- Benefits aren’t guaranteed by the research team.
- They have the right to exit the clinical trial at any time.
- The study may not follow standard medical procedures.
- How the study will be conducted
- Know that your participation is entirely voluntary.
- At any point during the study you have the right to stop your participation in the trial.
- Know that you can ask question, voice out your concerns before enrolling for a study.

Voluntarism

- This is the ability of an individual to judge, freely, independently, and in the absence of coercion, what is good, right, and best subjected to his/her own situation, values.
- Voluntarism of an individual may be affected by various factors such as intellectual and emotional maturity to make complex decision; illness-related considerations such as psychological effects of dreaded or incurable diseases or severe mental disorder and undue influence or coercion for research.

Process of obtaining informed consent

- The process involves the Researcher reviewing the consent form and relevant study information with the participant and verifying the participant's comprehension of the content.
- The Researcher should relate to the participant all the important aspects of the study, including the written information
- Open ended questions tend to be the best way to test understanding as they require feedback from the participant. If all reasonable attempts have been made to help them understand yet it is clear they do not, even if they are willing to, they should not be included.

Process Contd.

- If the researcher does not speak or read the language of the participant they are not allowed to consent the person without an impartial witness who does understand the participant's language.
- The informed consent form should be signed by the participant and by the researcher before the person can take part in the study.
- Informed consent which is an on-going process begins before the informed consent **form** is signed and continues until the participant has completed the study.
- Informed consent must happen before any study

Who Can Sign a Consent Form ?

- Informed consent should be signed and personally dated by the subject, or by the subject's legally acceptable representative, and the person who conducted the informed consent discussion.
- People from 18 above are independent adults and can give consent to be in a study; exceptions to this include individuals with mental incapacities.
- Minors who are married and/or are parents may be accepted as an emancipated minor.
- Adolescents consent is taken from the parent/guardian and assent from the adolescent.
- Assent is the affirmative agreement to participate in an activity
- Assent confirms voluntarily willingness to participate in the study.

Special Circumstances for Consent

When studies include individuals with mental incapacities, the person should be informed and if capable, should assent and sign the informed consent.

- For children less than 12 years of age, usually only consent from the parents is required.
- An impartial witness is used if the participant, or their legally acceptable representative, is unable to read or write

Special Circumstances Contd.

- Ethics guidelines outline five instances which allow for the enrolment of minors or those unable to make decisions for themselves. The conditions are:
- If the study objectives cannot be met using participants who are capable of giving informed consent.
- If the foreseeable risks to the participants are low.
- The negative impact on the participant's well-being is minimized and low.
- The study is not prohibited by law.
- The approval of the Research Ethics Committee is expressly sought on the inclusion of such participants, and the written approval covers this aspect.

Conclusion

- An Informed consent is a process where the clinical research participant must receive and comprehend information appropriately to make an autonomous decision.
- The four main principles of medical ethics are justice, non-malificence, autonomy and beneficence.
- Autonomy is the main ethical consideration underlying informed consent. The patients' right to determine what investigations and treatment to undergo must be respected by all. There are four elements of informed consent
- Signing an informed consent form is a written agreement that the subject or his representative fully understand the parameters of a given trial and are willing to participate in the study.

THANK YOU FOR LISTENING