Informed consent

Morenike Oluwatoyin Folayan
College of Health Sciences
Obafemi Awolowo University, Ile-Ife, Nigeria

Objectives

- To help participants understand what informed consent is.
- To discuss about the content of the informed consent document.
- To discuss the process of obtaining informed consent.
- To highlight the complexity of obtaining informed consent.

Outline

- Four elements of an informed consent document
- Eight minimal content of an informed consent document
- Processes for ensuring informed consent

Informed consent

- The doctrine of ‘informed consent’ is a cornerstone of ethical practice in research. It consists essentially of two parts:
  - a duty to **disclose adequate information** to the research participant before seeking his/her agreement to enrolment into a study
  - a duty to **obtain the voluntary agreement** of research participants before enrolment into the study.

Informed consent: principle of autonomy

- The purpose of the informed consent process is to allow prospective research participants to learn enough about the study to decide whether or not to participate.
- This demonstrates respect for persons' autonomy. It allows for independent decision making.
- Participation based on therapeutic misconception is not acceptable.

Informed consent process

- A process by which a research participant is helped to understand the research so as to be able to voluntarily confirm his/her participation having understood all aspects of the research.
- The process allow potential research participants to make an **informed decision** whether or not to participate in a research. It also grants the researcher the permission to enrol the participant and use obtained data for the **specific** or **future** studies.

Informed consent process - 2

- For prospective studies, the informed consent is an **ongoing** process NOT a one off process.
- Consent *process* is the discussion while the form is documentation of consent.
- Consent must be repeated, even informally especially for important, long and/or risky studies and/or easily misunderstood studies.

Informed consent process - 3

- Consenting process It should be interactive allowing the research participant time to ask questions and clarify misconceptions.
- Ideally, for multiple visit clinical trials, the informed consent document should not be signed on the day of administration: participants should have time to think through the document content before making a decision.

Informed consent process - 4

- The informed consent process should continue throughout the research.
- The research staff should continue to provide the research participants with information about the research during and after the trial.
- Inadequate information may invalidate the consent

Informed consent process - 5

- The informed consent process helps the research participant understand:
  - the goal of the project
  - what will be required of him/her
  - the potential risks and benefits in participating in the research
  - suitability to participate with respect to eligibility criteria

Elements of the Informed consent

- **Disclosure of Information**: this is provided by the research team.
- **Understanding (Competence)**: This should be assessed by the research team.
- **Voluntary Authorization**: this is given by the research participants.
- **Explicit/Formal Authorization**: this is in form of the signature of the research participant.

How to facilitate comprehension

- Use language that is understandable to and respectful of research participants or their legal representatives. Exclude scientific jargons
- Use of multiple mediums, pictures, visuals, audios to facilitate understanding.
- Ask questions to assess comprehension after the explanations.

Factors that affect voluntariness

- Voluntariness means being free from controlling influence.
- The study recruiter should not have undue influence eg the head of a sex brothel could unduly influence sex workers to participate in a research.
- Research could have elements of coercion. Participating in a HIV treatment study that implies no access to drug once participant leaves the study, is coercion.
- The compensation given to participants could also be an inducement.

Informed consent document

- Informed consent is documented by means of a written, signed and dated document known as the **informed consent form**.
- This document provides a summary of the research and explains the responsibilities of the researcher as well as the rights of the participants.
- The researcher and the participant each has a copy of the signed document: for the researcher, it is a legal document while for the research participant, it serves as a source of information.

Informed consent document - 2

- This document provides the research participants information about:
  - The goal of the research
  - Procedures and schedules
  - Study duration
  - Compensation
  - Confidentiality/anonymity
  - The risks and benefits associated with study participation
  - The study product
  - Voluntary nature of the project

Revised informed consent

- Research participants must re-consent during a study anytime there is a protocol revision or updated safety information.
- This is important as the information can affect participant suitability or willingness to continue in the study.
- The reconsenting process is the same as as the initial consenting process – explaination of the research, clarification of participants' concerns, signing of document.

Exemptions from informed consent

- When there is the need for emergency use of drugs in the following conditions:
  - The individual is confronted with a life threatening situation neccesitating the use of the test article.
  - There is no available alternative method of approved or generally recognised therapy that provides am equal or greater likelihood of saving the life of the individual.
  - Informed consent cannot be obtained due to inability to communicate with, or obtain legally effective consent from the individual.
  - Time is not sufficient to obtain consent from the individual's legal representative.

Challenges in Informed consent

- Informed consent is an unavoidably complicated issue for research associated with some challenge:
  - **Comprehension**: intellectual capacity. Insight is needed to provide a valid consent.
  - **Competence to consent:** Independence to exercise freedom of make choices is important.
  - **Benefit to participants**
  - **Environment where human rights are not respected**: respect for human rights and justice should govern the design and conduct of research.

Comprehension...

- Does adequate disclosure always result in comprehension?
- How is comprehension assessed or ensured and by who?
- How do you explain terminologies like ‘randomisation’, ‘placebo control’, ‘double-blinding’?

Competence to consent

- This is determined by:
  - Age of participant
  - State of mind and health of participant
  - Relationship to researcher
  - Community/third party role
- Competency is not black and white: you may have the capacity to make some decisions, but not others.

Third party role

- In some communities, it is customary to require the authorization of a third party, such as a community elder, in order for investigators to enter the community to invite individual members to participate in research.
- In situation where there is a cultural tradition of sharing risks and responsibilities, e.g. in some cultures where men hold the prerogative in marital relationships, where there is parental control of women, and/or where there are strong influences by community and/or religion or hierarchy.

Third party role - 2

- Authorization by a third party in place of individual informed consent is permissible only in the case of some minors who have not attained the legal age of consent to participate in research.
- In cases where it is proposed that minors will be enrolled as research participants, justification for their enrolment must be given, and their assent must be obtained in light of their evolving capacities.

Third party role - 3

- Community leaders or third parties give permission and not consent for study participation. Permission does not preclude consenting
- Where others have decision-making prerogative over a potential adult study participant, they can give assent for study participant's enrolment for study. The consent of the adult study participant supercedes the assent by the third party.

Minors and research

- Countries need to have their regulations on recruitment of minors
- Consent for children participation in research is given by their legally authorized representative. This is usually the parents or the legal guardian.
- Children 8-12 and older are able to give written assent for study participation after parents have given consent
- Emancipated minors are able to give consent for study participation.

In what circumstances will Informed Consent to research be unnecessary?

- The research or demonstration project is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payments for benefits or services under those programs, and the research could not practicably be carried out without the waiver or alteration.

Informed Consent Waiver - 2

- The ethics committees provides a waiver or alter some or all of the required elements of informed consent
- National ethics committees provide guidelines on consideration for informed consent waiver. Some research features considered for informed consent waiver include:
  - The research involves no more than minimum risk
  - The waiver will not adversely affect the rights and welfare of study participant
  - The research could not practicably be carried out without the waiver or alteration
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Special considerations for consent

- Clinical audit and epidemiological research - consent necessary for access to patients records unless data are anonymised and do not include any personal data.
- Stored human tissue and samples obtained in the course of treatment should only be used for research if consent has been expressly been obtained.

Thank you and QUESTIONS??