Informed Consent procedures and confidentiality aspects in clinical trials: specific issues in developing settings

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Outline of presentation

- Definition of Informed Consent
- Elements of the Informed Consent
- Types of Informed Consent
- Privacy
- Confidentiality
- Anonymity
- Protecting Privacy & Confidentiality
- Concluding remarks

What is an Informed Consent?

Definition of Informed Consent

- Informed consent (IC) is the voluntary decision by a competent person to participate in health research after being given all the critical information about the research
- Informed consent is a ***process*** which begins before and continues throughout the course of a research project

CIOMS guidelines definition of IC

- Council for International Organizations of Medical Sciences (CIOMS) defined informed consent as "**consent given by a competent individual who; has received the necessary information (verbally and in writing); has adequately understood the information; and after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation"**

IC and the principle of autonomy

- Obtaining the informed consent is a way of upholding the principle of autonomy
  - Freedom of choice
  - Respect of persons
  - Treating persons as ends in themselves and not as means to some ends
  - Researchers should not make use of information, samples or bodies of people without explicit permission given by the particular people concerned or their guardians

Pre-conditions for the IC

- **Competence** to process and understand information given

- **Voluntary willingness** to take part in the research

Elements of the Informed Consent

- Information elements
  - Disclosure of information by researchers (folder)
  - Comprehension of the information by the prospective participant
- Decision-making elements
  - Consent (agreement) OR Dissent (refusal) to participate in the proposed research
  - Authorization by the prospective participant
    - Signature or thump print

Types of Informed Consent

- Informed Consent is given by competent adults (above the legal age of majority)
- Proxy Consent is given by a guardian or legal representative on behalf of a person who is not competent to make decisions
  - Minors who are below the legal age of majority
  - Mentally retarded people
  - People in such serious health conditions that they cannot process information and decide
- Assent: if minors are mature ‘Assent’ may be required but it is not adequate on its own

Privacy and confidentiality

- What is privacy and confidentiality?

Privacy and confidentiality

- Is there any difference between privacy and confidentiality?

Privacy and confidentiality

- Why should privacy & confidentiality be protected?

Privacy & confidentiality and anonymity

- Is anonymity different from privacy & confidentiality?

Privacy

- Privacy means having control over the extent, timing, and circumstances of sharing aspects of oneself with others
  - That is control over one's body, biological samples from one's body or information about oneself
- Example

Confidentiality

- Confidentiality is the protection of the privacy of another person after the person has entrusted you with his/her private information or samples.
- In health research, the participant gives access to his/her privacy (samples or information) to specific researchers in a relationship of trust and with the expectation that it will not be divulged, without permission, to others.

Anonymity

- Anonymity means that the owner and donor of the private samples or information is not known
  - Unknown to both the researchers collecting the information or samples and users of the collected information or samples. Example: survey in a hospital without taking names or any personal identifiers of respondents
  - Unknown to users only, but the collector has the names and other personal identifiers of the participants (de-linked samples or information)

Protecting Privacy & Confidentiality

- There must be no disclosure of private & confidential information without informed consent of the owner of the information
- Storage should be secure with access restricted to authorized people only: including electronic data
- Secure room secure cabinets, etc
- Research procedures should not compromise privacy and confidentiality
- There should be rooms/places dedicated for screening, counseling, consenting, etc

Protecting Privacy & Confidentiality

- Publications, reports, websites, etc
  - The privacy and confidentiality of donors of samples or information must not be compromised
  - Names, pictures, contact details, etc may lead to the divulgence of particular participants
  - Some ERCs and NRAs scrutinize manuscripts before researchers can submit them for possible publication

Specific issues in developing countries

- Informed consent and privacy & confidentiality are affected by various factors prevailing in developing countries
  - Poor health delivery systems
  - Poverty on the part of participants
  - Poor infrastructure: e.g. environment in which informed consent is obtained may compromise validity of the informed consent process and also compromise privacy & confidentiality
  - Relatively low levels of literacy
  - Cultural practices that are mainly not individualistic

Concluding remarks

- Informed consent is written permission given by research participants to allow researchers to use information, samples, or bodies of the participants for research purposes
- Critical information should be explained to the prospective participants or their guardians to enable an informed decision to be made
- Informed consent upholds the principle of autonomy and shows respect for persons

Concluding remarks

- Every person has a right to control access to his/her body and personal information
- If a person gives his/her biological samples or personal information to a researcher, the researcher is obliged not to pass on the information to a third party without the person's informed consent: Privacy & confidentiality
- ERCs, NRAs and researchers should look out for research procedures that may compromise the privacy and confidentiality of participants

THANK YOU