INFORMED CONSENT

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Outline

- Objective
- Message
- Purpose of Informed Consent
- Elements of Informed Consent
- Discussion
- Conclusion

Objective

- To enable the learner identify the principal elements of the consent process particularly as implemented in the Nigerian National Code for Health Research Ethics

Message

- Informed consent protects research participant as well as researcher & the host institution

What is Informed Consent

- Researcher's autonomous authorization to participate in research procedure
- Based on the ethical principle of autonomy or respect for persons.

What is Informed Consent

- “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.” [Belmont Report, 1979.]

Why Informed Consent

- To meet standards required in bioethics
- To ensure that patients understand the objective and nature of a study, risks and benefits involved in their participation

Why Informed Consent

- To prove that participant's decision to participate was made willingly without pressure
- To protect the researcher and the host institution against legal prosecution

Elements of Informed Consent

- Capacity
- Disclosure and Understanding
- Voluntariness (in deciding)

Capacity

- Ability to understand information that is relevant to making a decision to participate in research
- Ability to understand the potential consequence of decision or lack of decision
- Decision not based on delusions or depression

Capacity

- What information must be understood
- What level of understanding is adequate
- Capacity influenced by adequacy of disclosure

Disclosure of Information

- Researchers are obligated to disclose a core set of information to participants
- Information provided by researcher is the basis for participant's informed decision making

Required Elements

- Purpose of the research
- Duration of participation
- Procedures to be followed
- Procedures which are experimental
- Confidentiality
- Justice
- Foreseeable/unforeseeable risks & discomforts
- Reasonably expected benefits

Content of Information

- Facts that participants usually consider important
- Facts that researchers consider important
- Purpose of seeking consent
- Nature and limits of consent
- Nature of research procedure
- Expected benefits of the research
- Risks of the research

Voluntariness

- The extent to which decision is free of any undue or controlling influence

Types of Influence:

- Intentional influence
  1. Persuasion: Appeals to reason
  2. Coercion: Use of explicit/implicit threats
  3. Force: Use of physical restraints/ sedation
  4. Manipulation:
     - Deliberate distortion or omission of information
     - Offering significant inducement

Types of Influence

- Circumstantial influence
  1. External e.g. Timing, location of consent process
  2. Internal e.g. psychological factors

Exceptions

- People with low capacity to make decision or vulnerable population
  - Children
  - Pregnant women
  - People with mental disability
  - Prisoners

The Informed Consent Process

- Start with interview
  - Verbal
  - Written
- Questions and answer sessions

The Informed Consent Process

- Participants choose voluntarily
- Contact address and phone number of researcher
- Signature documenting consent with date

Questions

- What is the role of researcher obtaining participants' consent for treatment?
- Should researchers obtain consent before commencement of data collection?
- What is the implication of the failure to obtain consent before commencement of data collection?

Conclusion

- It is the responsibility of the researcher to ensure that due processes are observed in obtaining the consent of participants before any research procedure is administered

- Protecting participants' interests is the soul of good research practice.