Voluntariness in Consent Process, & the Right & Procedure for Participants' Withdrawal

By

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Introduction

- Voluntary informed consent is universally accepted as a precondition for scientific research involving human beings.
- National and international guidelines for ethical conduct in research outline specific requirements for obtaining informed consent.
- Despite the promulgation of ethical guidelines, their application can be difficult in practice.

Introduction

- People were included as research participants without giving consent to participate in such studies.
  - E.g
    - as a result of the Thalidomide study in Europe in the 1950s, 12,000 babies were born with severe deformities due to thalidomide.

Meaning of Voluntariness

- Derived from the adjective voluntary
  - Of your own free will or design;
  - done by choice;
  - not forced or compelled
- Voluntariness
  - the extent to which an individual's decision was made by free will, devoid of compulsion or coercion.
- This implies that an informed consent process in research should be devoid of psychological compulsion, at the same time ensuring absence of constraints

Factors that Affect Voluntariness in Informed Consent Process

- ✓ Imbalance in physician/researcher-participant social or economic status
- ✓ Poverty
- ✓ Gender
- ✓ Age
- ✓ Socio-cultural setting
- ✓ Limited choices

Factors that Affect Voluntariness in Informed Consent Process

- ✓ Educational status/Illiteracy
- ✓ Psychological impairments /psychiatric disorders
- ✓ Debilitating diseases/quality of life
- ✓ Threats/coercion
- ✓ Deceptions
- ✓ Emotional issues e.g. relationships, love, etc.

Communication & Voluntariness

- Language barriers.
- Low levels of trust in
  - researcher(s)
  - sponsor
  - Institution
  - link –person
  - or where signatures are seldom used for conducting business.
- Family members or community leaders may have an important role in determining participation in health research.

Voluntariness & Autonomy

- Autonomy:
  - self rule, power to govern or maintain control over self
  - no external person or circumstance should govern an individual
- Request for participation in research should be based on the free will of the individual without subtle external manipulation

REC Members & Voluntariness

- HREC members determine the voluntariness of an informed consent process in research.
- Research proposal should affirm that participants have the following rights
  - ✓ participation is voluntary
  - ✓ refusal to participate is voluntary
  - ✓ Withdrawal of an initial decision to participate in research is voluntary

Informed Consent Document & Voluntariness

Document should:

- ✓ Be concise to avoid reader's fatigue
- ✓ Be designed to facilitate recall of pertinent information
- ✓ Be devoid of unnecessary repetitions, legalisms, unexplained scientific jargons
- ✓ Avoid truth dumping
- ✓ Enhance readability-
  - ✓ Prototype :http://www.nhrec.net

Informed Consent Document & Voluntariness

Document should:

- ✓ Highlight information about Risks and potential benefits
- ✓ Describe potential benefits after risks so that participants have an idea of one before the other
- ✓ Mention how confidentiality will be maintained
- ✓ Clarify appropriate inducement –compensation for lost daily wages, transport cost, refreshments, “care package”

Informed Consent Document & Voluntariness

Participation is:

- ✓ Voluntary
- ✓ Refusal to participate does not compromise the rights of the patient to continue to receive care
- ✓ Signing the consent does not amount to waiver of personal rights in any way

Withdrawal of Participation in Research

- Participants' wishes to withdrawal should be respected
- Should be voluntary.
- should be protected

Specifics About Withdrawal

- Data that is already contributed may not be withdrawn as it may have been transformed or used already
- It may have been presented at meetings, seminars or even published
- Such withdrawal may be unjust to those left in the study if it renders their participation useless

Evidences About Withdrawal–Marshall, et al (2006)

- Most respondents recalled being told that participation was voluntary & reported that they did not feel pressured to participate.

Evidences About Withdrawal–Marshall, et al (2006)

- Fewer Nigerian respondents reported that they could withdraw from the study at any time.
  - ✓ that some Nigerian participants were not given information about withdrawal from the study during consent or that they simply could not recall, perhaps they did not consider it important
  - ✓ participants' misunderstandings or concerns about refusing to join or withdrawing after enrollment
  - ✓ they thought that once they enroll, they will not be allowed to withdraw
  - ✓ They thought that withdrawal would hinder their medical care

Summary

- Informed consent for participation in scientific research relies on the concept of individual autonomy and personal decision making.
- In settings such as Nigeria, particularly rural communities, some women may seek permission from their husbands before giving consent.
- However, the need for spousal permission does not necessarily diminish the potential for voluntary participation in research.

Summary

- Although international guidelines for biomedical research emphasize that in some settings community leaders may influence in deciding whether or not community members should be involved in a study
- There is little empirical evidence to suggest that individuals personally seek permission from local authority figures.

Conclusion

- Trust remains at the center of our relationship with research participants
- There must be transparency in all matters relating to the research enterprise
- Clear description of the goals, risks, benefits, alternatives to participation and voluntariness are required in researcher-participants' relationship
- Creative approaches may be necessary for effective representations and involvement of communities and researchers

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