INFORMED CONSENT: PRINCIPLE, CONSTRUCTION PROCESS, IMPLEMENTATION AND CHALLENGES

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2. Purpose of Informed Consent
3. Elements of Informed Consent
4. Process of informed consent
5. Discussion
6. Case Study
7. Conclusion

OBJECTIVE

- Participants identify required process for consent implementation particularly as applicable to the Nigerian National Code for Health Research Ethics

DEFINITION (1)

- Informed Consent could be defined as: A research participant's autonomous authorization of a research procedure.
- Informed Consent is based on the ethical principle of autonomy or respect for persons.
- "Respect for persons requires that research participants, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them." [Belmont Report, 1979.]

"Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation." CIOMS 2002

http://www.cioms.ch/frame_guidelines_nov_2002.htm Accessed on May 9, 2016

Still on consent

Informed consent is the knowledgeable authorization by a research participant or patient (in the case of clinical practice or study) to authorize research participation or medical intervention, and one that is in accord with the participant's or patient's values and preferences; or in biomedical research, a process by which a prospective participant indicates his or her willingness to be part of a research or study

Purpose of informed consent

Emanuel et al. (2000: 2706) identify a 2-fold purpose of I/C as follows:

"to ensure that individuals control whether or not they enroll in clinical research and participate only when the research is consistent with their values, interests, and preferences."

STILL ON PURPOSE

- To protect patients/research participants from exploitation by investigators
- To protect researchers/sponsors/institutions from unnecessary litigations arising from research
- To ensure that research is conducted according to accepted ethical norms or principles
- Serves as a statement of contract between researchers and participants

Grounds for informed consent

Robert Levine argues thus:

"the firmest grounding for the requirement to seek consent is the ethical principle 'respect for persons'- a principle which, when interpreted in a Kantian sense stipulates that research subjects will be treated as an end and not merely as a means to another's end"

Philosophical basis of I/C

- Based on several lines of philosophical reasoning: the need to protect and maintain human dignity
- Based on the Hippocratic admonition "to help, or at least, to do no harm"- a way to promote patient or subjects' benefit and welfare

PHILOSOPHICAL BASIS OF I/C

- I/C can be justified on the grounds of social benefit: producing the "greatest good for the greatest number" (utilitarianism)
- Based on the ethical norm of "respect for persons"- not to treat persons as means but as ends (Kantianism)

Religious basis for I/C

Some basic tenets of religions provide a basis for informed consent, e.g., the teaching that each individual's life is a gift from God and is of infinite worth (the "sanctity of life")

LEGAL BASIS

The Nuremberg trials and sentencing of Nazi physicians after WW II and some other cases of litigation arising almost exclusively in the context of medical practice provide legal grounding for informed consent, e.g., a 1914 legal judgment in America: *Schloendorff v. Society of New York Hospital*

The *Schloendorff v. Society of New York Hospital* case is one about court findings that surgery ought not to have been performed on a patient who had agreed to an abdominal examination under anaesthesia but had declined an operation

THE LEGAL BASIS (3)

In the famous statement which eloquently expressed the view of the right of competent people to self-determination, the Judge demurred, saying:

> *Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault.*

Elements of informed consent

Beauchamp and Childress list key elements:

I. **Threshold Elements**

1. Competence (to understand and decide)
2. Voluntariness (in deciding)

II. **Information Elements**

3. Disclosure (of information)
4. Recommendation (of a plan)
5. Understanding (of 3 and 4)

III. **Consent Elements**

6. Decision (in favour of plan)
7. Authorization (of the chosen plan)

Threshold Element: Competence

- What is competence?
  - Being rational?
    - Using reason to pursue your own goals?
    - What about the person who carefully figures out how to pursue his project of dismembering himself?
  - Having the right goals?
    - A competent person reaches reasonable conclusions based on reasonable goals?
    - There's a danger of paternalism here

Competence

On the role of competence in decision-making, Miller and Rosenstein (1999, S:432), say:

"Persons who are determined to lack, or have severe impairments in, decision-making capacity are either excluded from research or enrolled on the basis of protective procedures such as advance directives consenting to research, completed when the subjects were capacitated and/or authorization by a designated surrogate decision maker"

- See Miller F. G., (1999), "Independent Capacity Assessment: A Critique," University Publication of America

Voluntariness (in deciding)

- A person acts voluntarily to the degree that he or she wills the action without being under the control of another's influence
- Some factors that hinder voluntary action: debilitating disease, mental impairments, drug addiction, etc.
- Manipulation and coercion can affect voluntary action
- Many influences are resistible, and some are welcomed rather than resisted

Information Element

Disclosure (of information)

- This is the basis of decision making for participants
- Researchers and professionals are under obligation to give adequate information about research to participants
- In seeking to promote understanding, investigators should take into account the educational level of research participants

What is adequate disclosure?

- **3 Standards**:
  1. Research Community: What a typical researcher would disclose
  2. Participant: What the participant wants to know
  3. Objective: What a reasonable person would want to know

INFORMATION DISCLOSURE

The core set of information include:

i. Facts that patients or participants consider important in order to make decision

ii. Information that the professional considers to be important/the professional's recommendation

iii. The purpose of seeking consent, and

iv. The nature and limits of consent as an act of authorization

Consent Elements

- Prospective research participants should be allowed time to reach a decision
- Consent should be voluntary and not coerced
- The consent form can be signed in the front of witnesses, or in the case of non-literate people, thumb printed before witnesses

Factors Influencing comprehension

- **Use language** – exclude scientific jargons - that is understandable to and respectful of research participants or their legal representatives.

- Use multiple approaches - pictures, visuals, audios - to facilitate understanding.

- Ask questions to assess comprehension after the explanations.

Consent as an ongoing process

- Informed consent is a continuing process, and not a once-for-all process that is accomplished once the participant has signed the consent form

- Signing of consent paper does not mark the researchers' obligation to research participants. HREC should ensure that investigators/researchers abide by all the details in the consent agreement with volunteers or prospective research participants

FACTORS INFLUENCING VOLUNTARINESS

- **Voluntariness:** means being free from controlling influence.
- **Undue influence of the researcher:** This could have undue influence eg the head of a sex brothel could unduly influence sex workers to participate in a research.
- **Coercion**: Researches could have elements of coercion.
- **Compensation**: The type of compensation given to participants could also be an inducement.

INFORMED CONSENT DOCUMENT [1]

- 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 this 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 reconsent during a study process 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 and there are certain challenges.
  - **Comprehension**: intellectual capacity, insight is needed to provide a valid consent.
  - **Competence to consent:** Independence to exercise absolute freedom of choice 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'?
- How does age, the state of mind and health, relationship to researcher affect comprehension?
- What are the roles of the community/third party in obtaining consent?

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

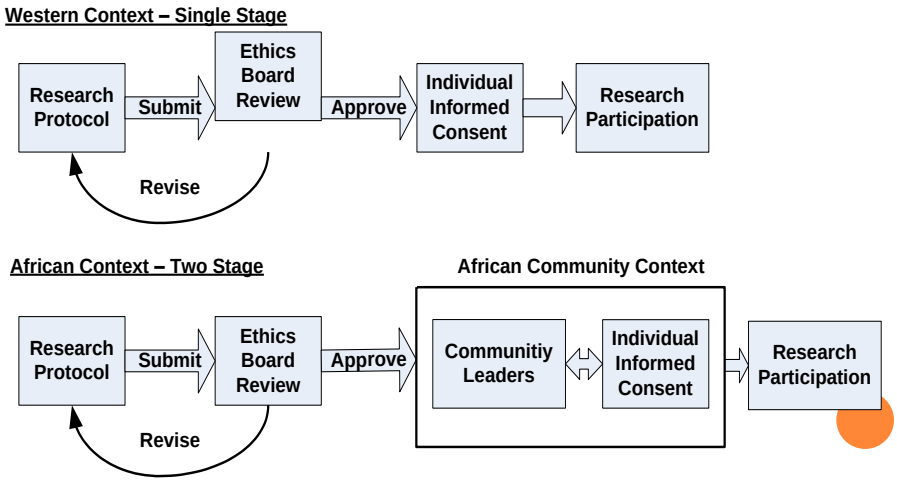
- Authorization by a third party in place of individual informed consent is permissible only in the case of some minors who have not attained the legal age of consent to participate in a research.
- In cases where it is proposed that minors will be enrolled as research participants, specific and full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

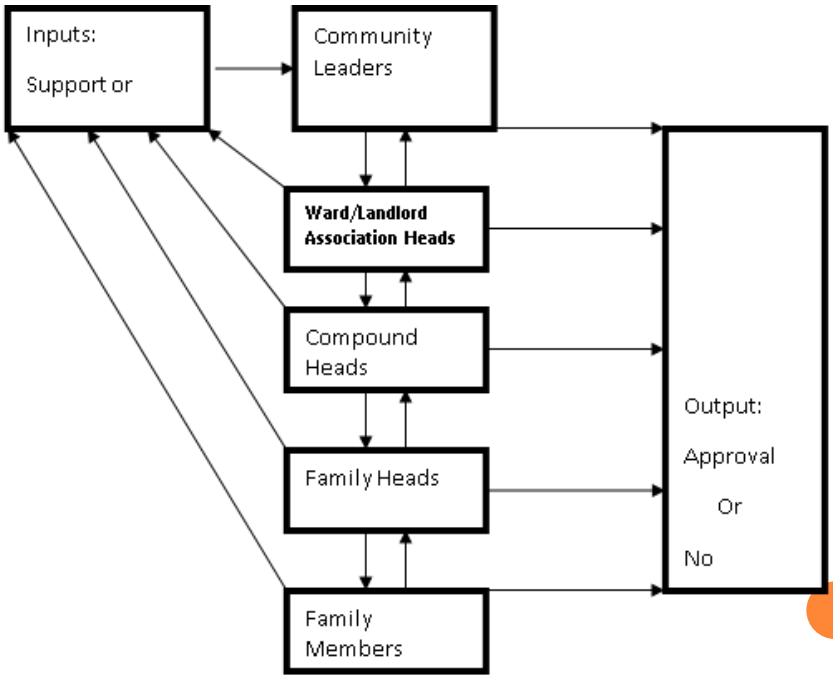
Researchers Responsibilities in Consent Seeking

- Entering "communities" for health research requires special skills
- The problems confronted by researchers differ from one community to another.
- There are different types of Communities including easy to reach (students), hard to reach (drug users).

Locus of Decision Making

Figure __. Access to Research Populations: *Differences in Context*





Considerations for Gaining Access into Community

- **Community level:**
  - social organization
  - political system
  - world view
- **Individual Level:**
  - belief system
  - gender
  - family structure
  - social networking

General:

- Comprehension of information
- Perceived benefits and harms
- Researcher's reputation
- sponsor's reputation
- research antecedents
- institutional integrity.

Considerations for Gaining Access Hierarchical Consent in Africa

- The gatekeepers:
  - Chiefs
  - Husbands
  - Parents/In-laws of Adults

No consent for enrolment of participants simply means permission to enter.

Note: Abuses may occur preventing individual consent

- *Individual Consent*

Cultural Ethical Concerns In Consent Giving

- Customs, traditions, moral values vary worldwide
- Cultural norms & traditions guide the views of individuals, communities & society
- Shapes actions of individual Communities & Societies for right and wrong
- What is right in one society may be wrong in another.

Challenges of Consent Seeking Contd.

- Researchers in developing Countries are under pressure to recruit as many study participants as possible in a short time.
- Belief that study populations do not know their rights anyway
- Perception that researcher is doing study participants a favour

Challenges of Informed Consent Giving Contd.

- Doctors and sometimes other researchers are regarded as **little '*gods*'.** Hence Lack of will to challenge medical or learned authority.
- Gullibility (innocent participants comply with any dictated terms without questioning)
-
- Poverty syndrome- a need for care

Informed Consent Giving: Impact of Literacy and Culture

- Lengthy and complicated Protocols in a 20% literacy Community.
- Translation and back translation of scientific terms (genes, recombinant DNA etc) to several local languages.
- African customs relegate women to the background and not expected to take unilateral decisions.
- Poverty wears a female face – hence the tripartite relationship of poverty – child labour and – a struggle through life does not augur well for individual consent by women (World Bank 2004).

Probing Questions by Research participants in Developing Countries -I

- Who are these people conducting the trial?
- What is theirs real interest?
- Why are health care facilities so inadequate in our community?
- Why is such a large team with huge facilities interested in studying us?
- Is this for the researcher's benefit or ours?
- How will our lives change if tests are positive for enumeration in research?

Probing Questions by Research participants in Developing Countries -II

- What happens to us if we refuse to participate?
- What happens to us after clinical trials if we accept participation?
- Will we be better off if we participate?
- What effect will clinical trials have on our babies (if not breast fed in HIV test cases)?
- What will our spouses (*husbands*) say about participation?

Probing Questions by Research participants in Developing Countries-III

- Who can we consult for answers to these myriads of questions?
- Can we rely on all explanations by the researchers?
- Should we consult the leaders in our community?
- Should our community leaders decide if our members should participate in the trial or must we decide all by ourselves?
- If researchers encourage us to participate, how will the decision affect our relationship with our community?

Informed Consent Giving:
Impact of Literacy and Culture on Contd.

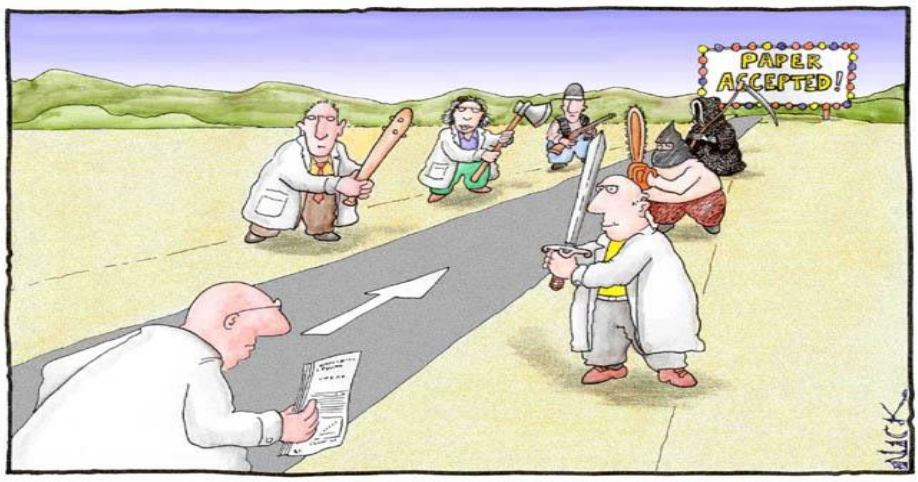
- Many Africans and Nigerians in particular, are usually skeptical of written documents and evade them because of some local reasons.
- Most participants prefer verbal consent This does not go well with the principles of good documentation of consent expected in international research

Informed Consent Process: Conceptual Relativism

- Culture lacking concept of individual human rights
- Culture lacking concept of the gender equality
- Cultures where authority of leaders is basis of judgment
- Cultures with beliefs of ancient or religious texts

Cannot understand, accept or respect, voluntary concept of the individual or <u>even more so</u> gender equality in Consent. Cannot easily accept modern international concepts for decisions in Informed consent.

Informed Consent: Complementary Role of RECs



Most scientists regarded the new streamlined peer-review process as 'quite an improvement.'

Informed Consent: Role of Research Ethics Committees

- RECs must focus on the ability of researchers to spell out info to facilitate Informed consent.
- RECs should be empowered to adopt basic Ethics principles & universal minimum standards of care in research.
- RECs must focus attention on protection of individual research participants through informed consent at a confidentiality level.

Informed Consent Process : The Way Forward

- Establish functional independent national and institutional research ethics committees.
- Train and empower researchers
- Provision of effective health care services to enable implementation of required Standard of Care by researchers and clinicians.
- Political will for funding and implementing research ethics code at all levels of governance.
- Resources for monitoring aspect of research ethics committee's oversight functions

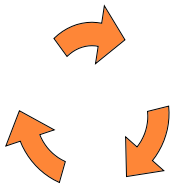
ETHICAL QUESTIONS

- What is the role of researcher in obtaining consent from participants?
- Should researchers obtain consent before commencement of data collection?
- What is the implication of failure to obtain informed consent before commencement of data collection?
- How do researcher address cultural issues in consent process?
- What is the role of law in informed consent management?

CONCLUSION

- It is the duty of the researcher to ensure that due processes are observed in obtaining the consent of patients before any research procedure is administered.
- Protecting research Participants' interests is the soul of good research/clinical practice.

- QUESTIONS, COMMENTS, AND DISCUSSION



- THANKS FOR PARTICIPATING