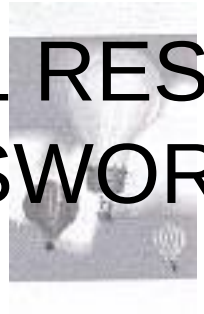
Ethical and Legal implications of research on human subjects

By

ANARADO, A.N

GLOBAL RESEARCH NURSESWORKSHOP



PURPOSE OF PRESENTATION

1. Provide basic understanding of the
- Rights of humans as subjects of research
- Helsinki Declaration of the World Medical Association (WMA)

2. Discuss the concept of informed consent

3. Discuss the application of principles of informed consent in research with human subjects

Research with human subjects

- Humans have rights-respect for person, life, dignity, privacy, self determination, etc.
- Humans are now more informed and politically conscious than ever before.
- Research has advanced science and technology as well as medical/health practice
- Research with human subjects has ethical and legal implications (can violate human rights, has risks and burdens)
- Practice must be controlled and guided by certain principles

Principles guiding research with human subjects

- **Needs a framework that combines:**
  - **The applicable regulatory requirements**
  - **Good Clinical Practice**
  - **Ethical Principles – Declaration of Helsinki of the World Medical Association**

Principles guiding research with human subjects

Four basic sources of rules of the road for the responsible conduct of research on human subjects

- **professional codes,**
- **government regulations,**
- **institutional policies, and**
- **personal convictions.**

Research with human subjects

Informed consent

- Ethico-legal framework
- Pre-condition for research on human subjects
- Guiding principle in clinical decision making

What is informed Consent?

- A **process** by which a **person confirms his/her willingness** to participate in a **procedure, treatment or research**

- After having been provided with all **relevant information** that will enable one take **decision to participate**

Informed Consent of Research Subjects: Requirements

- **Prior to the beginning of the study, the investigator should have the IRB/IEC's written approval of the written informed consent form and any other written information to be provided to subjects.**
- **Any revised written informed consent form should receive the IRB/IEC's approval in advance of use.**
- **The subject or legality acceptable representative should be informed in a timely manner if new information becomes available that may influence subject's willingness to continue in the study.**
- **The communication of this information should be documented.**

Informed Consent of Research Subjects: Requirements

- **The investigator or trial staff should not coerce or unduly influence a subject to participate or continue in a trial.**

- **None of the oral or written information should contain any language that causes the subject to waive any legal rights, or that releases the investigator, institution or sponsor from liability for negligence.**

Informed Consent of Research Subjects: Requirements

- **The investigator should fully inform the subject of all pertinent aspects of the study including written information and IRB/IEC approval.**

- **The language used in the oral and written information should be as non-technical as practical and understandable to subject, or legally acceptable representative and impartial witness, where applicable.**

Informed Consent of Research Subjects: Requirements

- **Should provide the subject ample time to inquire about details and decide whether or not to participate in the study. All questions must be answered to the satisfaction of the subject.**

- **Prior to a subject's participation in the study, the written informed consent form should be signed and personally dated by the subject and the person who conducted consent discussion.**

Informed Consent of Research Subjects: Requirements

- **If a subject is unable to read:**
  - **The written information is read and explained**
  - **The subject orally consents freely**
  - **If capable, subject personally signs and dates the informed consent form**
  - **An impartial witness signs and personally dates the consent form to attest the above**

- **The subject should receive a copy of the signed and dated written informed consent form and any other written information and a copy of their updates, if any.**

Informed Consent of Research Subjects: Requirements

- **When a study includes subjects who can only be enrolled with the consent of the subject's legally acceptable representative (e.g. minors, severe dementia), the subject should nevertheless be informed up to subject's understanding and, if capable, sign and personally date the written informed consent.**

Informed Consent of Research Subjects: Requirements

- **A non-therapeutic trial should be conducted in subjects who personally give consent and who sign and date the consent form.**

  Exceptions:

  - **The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally.**
  - **The foreseeable risks to the subjects are low**
  - **The negative impact on the subject's well-being is minimized and low**
  - **The trial is not prohibited by law**
  - **The approval of IRB/IEC is expressly sought on the inclusion of such subjects**

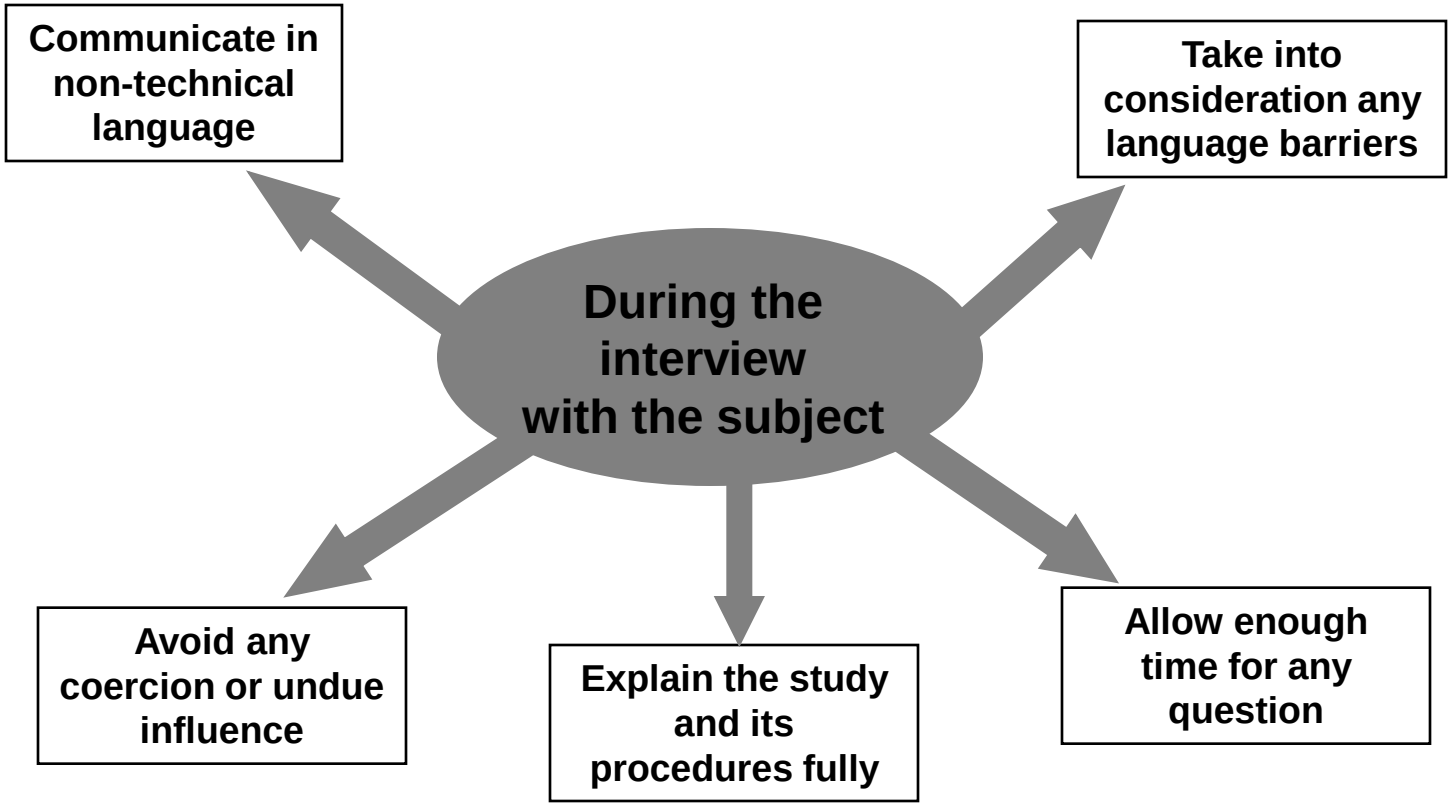
  In those cases the subject's legally acceptable representative will sign the form.

Informed Consent of Research Subjects: Requirements

- **In emergency situation, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative should be requested. If the later is not available, enrolment should require measures described in the protocol, with documented IRB/IEC approval to protect the rights, safety and well-being of the subject.**

The subject or the representative should be informed about the study as soon as possible and consent to continue

The Informed Consent Procedures



The Informed Consent Procedures

- **Reverse the roles!!!**
- **You shouldn't be involved in a trial unless you would be willing to be randomized yourself if you had the study disease!!!!!**

The Informed Consent Procedures

Points which should be explained to the patients during the IC process.
Some of the key points include…

The trial

- ✓ The research nature of the study
- ✓ Purpose & number of subjects
- ✓ Procedures
- ✓ Length
- ✓ Responsibilities

Investigational product

- ✓ Risk & benefits
- ✓ Alternative treatment options

The Informed Consent Procedures

- **Specific issues to inform the subject of their rights include:**
  - **That their participation is entirely voluntary**
  - **That they may refuse/withdraw at any time without penalty**
  - **That they must be informed of any new findings that may affect their willingness to participate**
  - **That they are given adequate time after the interview to consider and discuss their participation before signing**
  - **Who to contact for further information**

The Informed Consent Procedures

The following people may be involved in the IC process.

- **From the study team**
  - **Investigator**
  - **Sub-Investigator**
  - **Appropriately delegated team member**

- **From the subject**
  - **subject**
  - **subject's legally accepted representative**
  - **Witness**

The type of trial & the local regulations will dictate who must be present

The Informed Consent Procedures

- **If the subject is unable to provide informed consent then consent should be obtained from the subject's legally acceptable representative.**

- **Whatever the situation, the subject "should be informed about the study to the extent compatible with the subject's understanding and if capable, the subject should sign and personally date the written IC form".**

The Informed Consent Procedures

- **There are special requirements governing IC in cases when the subject is…**
  - **A minor**
  - **Not legally competent**
  - **Illiterate**
  - **Unable to give IC owing to the nature of the trial/condition (e.g. emergency situations, severe dementia).**

The protocol and/or the local legislation may identity other cases where there are special requirements for IC

The Informed Consent Procedures

Special considerations apply to the IC process in genetic Research

- **The additional IC form for the genetic part of the trial will include:**
  - **The protection of subject genetic data (access, archiving, destruction procedures & future use by third parties)**
- **The investigator will need to discuss:**
  - **The genetic component of the trial**
  - **Risk & potential benefits**
  - **How to handle any incidental findings**

The Informed Consent Procedures

The IC form

Sign and date → **subject (and/or representative/ witness) and person who conducted the interview**

Copy → **subject (and/or representative/ witness) receives copy of form prior to study participation**

File → **Investigator is legally bound to keep a copy of the informed consent form**

The Informed Consent Procedures

Subjects must re-consent if protocol amendments are made that may affect their willingness to continue