Ethics Matter: Elements of Informed Consent and the Process of Obtaining It

Source: WHO Research Ethics Review Committee

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Objectives

1) Review contents of informed consent templates

2) Process of obtaining informed consent

Different Kinds of Informed Consent

- Qualitative studies
- Clinical studies
- Parental consent for research involving children/minors
  - Clinical
  - Qualitative
- Informed assent for children/minors
- Storage and future use of unused samples

Key Elements of Informed Consent

- Introduction
- Purpose of Research
- Type of Intervention
- Participant Selection
- Voluntary Participation
- Procedures
- Duration
- Risk/ Benefits
- Reimbursements
- Confidentiality
- Sharing the Results
- Right to Refuse or Withdraw
- Who to Contact
- Certificate of Consent

Can more than one informed consent be required?

- Depending on the study design one study may require more than one form of informed consent
  - You may need to obtain informed consent from:
    - local authorities, health service providers, and study participants/constituents

Why do we seek informed consent?

- Participants must give their individual consent to participate in a study
- Not just obtaining a signature
- Opportunity to address questions, concerns and share study information
- Few types of studies that do not require informed consent
  - Ethics review committees must waive the requirement

National/Regional Ethics Bodies (IRB/PHSC)

- Be aware of research guidelines existing in your country
- Consult regional/national IRB research institutions
- When appropriate, consult with local leadership or representatives of populations
- Be prepared to discuss benefits of research to the population

Don't forget the IRB!

Researchers should always submit their proposals the national IRB of the country where they are conducting research.

Also check with your home institution!

Relationship with Community Leaders

- Obtaining agreement from community leadership for a study is good practice and sometimes mandatory
  - Does not replace the consent of individuals!

- Community consent is often acquired through dialogue, though some locations require written evidence
  - It is your responsibility to be aware of community requirements

Recruiting and Informing Research Participants

- Recruit individually or in small groups
- Broader approaches can be more effective
  - Posters, brochures, community meetings

Informing Potential Participants

- Cater to your audience
- *Information shared with potential participants must be presented in an understandable manner*
  - Their ability to give informed consent depends on their level of understanding!

Understanding and Respecting Your Study Community

- Degrees of autonomy varies among different cultures
  - Seek informed consent from individuals while keeping culture in mind
- Only an individual can give their consent
- Respect those who are reluctant to participate

What about verbal consent?

- Acceptable with illiterate or those who cannot sign a form
  - Must ensure that information provided is clear and a witness is present

- *There are very few cases, other than illiteracy, when verbal consent is acceptable and these always require IRB approval*

Obtaining Informed Assent in Research with Minors

- First you must determine that equivalent research cannot be conducted on adults
- Obtain parental/guardian consent for all minors
- Minors who are old enough (emancipated minors) to understand study information should:
  - Be informed of research study
  - Have any questions answered
  - Be able to express their agreement or lack of interest in the form of informed assent

Obtaining Consent from Vulnerable Populations

- Ensure participants will not be exploited
  - Situations that compromise dignity and safety
- Make sure that consent is genuine
- Research should not place added risk or stress on participants

Is it okay to pay participants?

- You should not provide incentives to participate

- Participants can be reimbursed for:
  - Expenses incurred as a result of research
  - Lost time at work

Who obtains informed consent and from whom?