Clinical Observer Training
Session 5
How Do I Obtain Informed Consent?

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MCHIP Maternal and Child Health Integrated Program

Session Objectives

At the end of this session, participant shall be able to

- justify the importance of informed consent,
- describe the process for obtaining informed consent,
- demonstrate obtaining informed consent in simulation, and
- review the informed consent tool.

Past Experience

- Can you recall a time when something was done and you were not informed or asked for permission?
- How did it make you feel?

What Is Informed Consent?

- Voluntary
- Informed
- Understood

When Is Informed Consent Needed?

Informed consent MUST be obtained from all individuals

- undergoing a procedure with risk of harm and/or
- participating in research.

Research Study Consent Forms

A research study consent form must include:

- purpose of the study,
- what the participant is being asked to do,
- potential risks and benefits,
- how much time is required,
- participation is voluntary, and
- invitation to ask questions about the study.

Using Approved Consent Forms

- Written informed consent must be obtained using the consent forms that were submitted to the institutional review board (IRB) that reviewed the research study (when applicable).
- Most IRBs will provide a stamp or seal on the approved consent forms; it is important to use these versions.

Types of Informed Consent

There are two types of informed consent:

- Written
- Verbal (preferred unless the IRB requires written)

Other Consent Processes: Mobile

- Read aloud and mark response on smartphone.
- Consent must be obtained for each participant interviewed. No names are recorded.
- Ask next of kin for consent if clients are unable to provide consent themselves.

Informed Consent

…is vital to ensure that all patients and/or study participants understand the nature of the study and have voluntarily agreed to receive the procedure and/or participate in the research.

Test Your Knowledge

For a research study, informed consent is

1. necessary so that study participants understand the nature of the study and ensures voluntary participation in the research,
2. only necessary in some research studies, or
3. not necessary for study participants over the age of 18.

Demonstration and Practice

See handouts.

Thank you!

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