Consent & Assent in Research

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In association with: Grand Valley State University Office of Research Compliance & Integrity

What is informed consent?

Informed consent is the idea that people have the right to know important information about a study that pertains to their health, privacy and overall well-being before making a decision to participate in research or not.

This information includes:

- Risks
- Benefits
- The purpose of the study (in some cases)
- The duration of the study
- The kind of information that will be collected

Historical Origins of Informed Consent

- Nuremberg Trials (1945 to 1946)
- Tuskegee Experiments (1932 to 1972)
- Declaration of Helsinki (1964)

Where is the ethical basis of informed consent?

There are four principles of medical ethics

- Respect for Persons
- Beneficence
- Nonmaleficence
- Justice

Informed consent is derived from the principle of Respect for Persons

What is the difference between consent and assent?

Consent

- For adults, primarily
- Occurs when a person who has reached the age of consent (18) agrees to participate in a study. However, age is not the only factor. The adult must also be deemed competent to give consent for participation.

Child Assent

- For children, primarily
- Occurs when a person who has not yet reached the age of consent (18) is given approval by a parent or guardian to participate in research. The child is then asked whether they would like to participate or not, at which time the child can assent or dissent (refuse to participate)

More about assent

- Note that assent is not always required in studies involving children. However, an Institutional Review Board (IRB) may ask that the principal investigator obtain assent

- Approval for participation by one parent or both parents could depend based on the type of study and the rules of the IRB
  - In studies that are greater than minimal risk and don't necessarily have direct benefit to benefit, then both parents need to give approval
    - Exceptions:
      - Parent unavailable/deceased
      - One parent has sole custody

- To assent, the child should have the capacity to understand basic ideas of the study such as what it involves and what is expected of them

- In instances where a guardian approves a child for involvement in a study but the child does not wish to participate, best practice is to not include the child in the study even if it is not legally or otherwise required to obtain assent
  - IRB needs to be very specific in making sure whether assent is required or not

What are considerations to take into account when trying to obtain consent or assent?

- Make sure the potential participant understands that participation is ALWAYS voluntary. Participants can withdraw from a study at any time and for any reason

- Make sure that the potential participant is given information about the study in a language that they understand. This might also involve making sure that the participant is literate in their primary language, if consent is obtained via written documentation

- If there is financial compensation for participation in the study, consider whether there might be undue influence put on potential participants, especially those from lower SES backgrounds

- Consider whether the participant belongs to a vulnerable population

Who are vulnerable populations?

A vulnerable population is a group of individuals who, owing to some internal or external limitation(s)/pressures, are unable to fully and freely give consent to participate

- Children
- Prison inmates
- Economically disadvantaged
- Educationally disadvantaged
- Individuals with diminished capacity to make decisions

Acknowledgements

Benjamin Vesper

Stacey Gardner

Jeffrey Byrnes

Sources

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