

Obtaining/Writing a Consent

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In research, the discussion of human subjects is an important part of any proposal and, as such, should go hand in hand with the issue of ethics when conducting research.

Streubert and Carpenter (1995) make reference to the ethical principles of all researchers to protect the rights of the public. In 1974 the National Research Act established the use of institutional review boards, whose primary responsibility is to safeguard the rights of individuals participating in research studies. Institutional Review Boards (IRB) consists of a group of individuals who convene to review proposed and ongoing studies with respect to ethical and safety considerations.

Individuals have the right of self-determination and the inherent right to be fully informed about research in which they voluntarily decide to participate. Prospective participants should be fully informed about the nature of the study and their participation in the study. It is essential that the researcher and those involved in the study appreciate that informed consent is an ongoing process. It begins even before the participant agrees to become a part of the study and continues throughout the entire study. This ongoing process of informed consent allows for ongoing interaction and discussion between the research team and the participants. It is the duty of the research team to keep the participants informed throughout the study.

Voluntary consent should be obtained in writing. As described by Windle (2002), the principle investigator is responsible for obtaining the written consent. The IRB will determine who can obtain the consent. Typically investigators are the people who can obtain the consent. These investigators are identified to the IRB and are authorized to obtain consent. Others who participate in the research should not obtain consent from participants unless approved by the IRB. If the study involves complex information the investigators should review the information more than once or allow for a period of time between the discussion and the signature of the participant. This step allows the participant to contemplate the proposed study with others.

The consent should be read aloud completely and also available in writing with the subjects. It should be written in a language that is understandable at the 6th-8th grade reading level. If the participant does not speak English, then the consent needs to be translated into the language of the participant. The use of audiotapes, DVDs and other written materials can be beneficial in assuring that the information is understood. In the informed consent process, the investigator should ask questions that are open-ended (questions that begin with what, why, describe to me more, etc) to reveal additional needs of the participant. Additionally the person obtaining the consent should have the potential participant verbally summarize the research and their part in it to assure the participant comprehends the study's risks and benefits. It is the responsibility of the researcher/investigators to ensure that the participant understands the study and its risk and benefits.

Polit, Beck and Hungler (2005) describe the required elements for "Informed Consent" documentation. They state that consent forms need to include a number of elements to be considered complete and comprehensive.

These elements include:

- Purpose of the study
- Description of procedures, if any, to be followed
- Identification of any experimental procedures
- The participant's time commitment
- Type of information that will be obtained
- Potential for physical or emotional discomfort
- How a potential injury (if indicated) will be treated
- Explanation of whether compensation or medical treatment will be available if injury occurs
- Methodology for protecting privacy and anonymity
- Names of resource persons for questions about the study
- A clear statement that participation is voluntary
- A clear statement that nonparticipation or withdrawing participation will not result in consequences or penalties

- A description of potential gains and benefits of the research
- Disclosure of alternative treatment options that may be advantageous to the subject

The language in the consent cannot include exculpatory language. The participant cannot waive their legal rights in the research study.

To have informed consent, individuals or groups participating in research studies receive a comprehensive explanation and description of the potential risks and benefits of their participation in the research study. Again, this is an ongoing process to allow individuals to stay informed of changes to the process, and an opportunity to withdraw their consent if they should choose to at any time without the threat of penalties or loss of benefits that the participant would be otherwise entitled. HIPAA regulations should also be considered in the language of the consent. The patient must be asked and provide written authorization for the use and disclosure of their identifiable information for research purposes.

By providing the ongoing opportunity and information as the study unfolds, the participants are able to renegotiate and remain a part of the decision-making process. This might occur when a couple gives permission for their child's surgical procedure to be videotaped. Informed consent allows them to change their mind in the event that the child becomes uncooperative with the videotaping procedure, so they may choose to withdraw their permission.

Research with children has special considerations. Most institutions require that the assent of a child 7 and older be obtained, unless their decision-making capacity is impaired. Assent is the child's affirmative agreement to participate in the study. Some institutions may allow children from ages 14-18 to sign similar forms to the parental consent forms. If the parent consents to the study, but the child does not provide assent then the child should not be a participant in the study. Articles are available to address many other ethical issues with children and research.

Special procedures and safeguards must be used with vulnerable groups. These groups include pregnant women, human fetuses and neonates. Prisoners are another group that requires special considerations. If you are planning research with these groups, please read the governmental requirements involved with these groups (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) .

Burns, N. & Grove, S.K. (2005). *The practice of nursing research: Conduct, critique, and utilization* (5th ed.). St. Louis, MO: Elsevier/Saunders.

Polit, D.F., Beck, C.T., & Hungler, B. P. (2005). *Essentials of nursing research: Methods, appraisal, and utilization*. (6th ed.). Philadelphia, PA, Lippincott Williams & Wilkins.

Struebert, H. & Carpenter, D. (1995). *Qualitative research in nursing: Advancing in the humanistic imperative*. Philadelphia: J. B. Lippincott Company.

United States Department of Health and Human Services. Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects. Available online: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

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