

NUREMBERG - The informed consent of the subject is absolutely essential.

If an individual's agreement is essential, how are studies conducted in groups of people who cannot consent such as children, the mentally infirm, people with dementia, or in cultures where autonomy of an individual is not recognized?

Proxy: The authority to act for another. The written authorization to act in the place of another

A proxy consent should be a consent based on what is thought that the person would do were that person able to decide autonomously. The proxy consent is given on behalf of that person. It should never be an easy decision.

Authority: States govern who can have authority to give proxy consent. Each state is different.

Minors

Although legally, a minor cannot consent to be in research, there is a very wide range in the decision making skills and information processing of minors from infants to risk taking adolescents. Although there are rules that modify this, each minor should be asked to participate in the consent process to the best of their ability.

Emancipated Minors

Each state defines emancipated minors and gives them rights. Most states allow a married minor the right to make decisions for themselves. Whether they can make decisions for their minor children is also up to state law.

Elderly

Just as with minors, the range of autonomy among the elderly is quite wide. Most elderly require support in some way - larger print, louder voices, vintage language - but are quite capable of decision making on their own. The ends of the spectrum are easy to determine; the person is vocal about capacity or has a guardian for such decisions. The group in the middle is more difficult and their needs should be carefully assessed.

Many elderly have, before losing their decision making skills, clearly stated their preferences regarding their care and treatment. This makes the job of the person making a decision on the elderly person's behalf much easier.

Decisionally impaired:

Some people, for medical or developmental or emotional reasons, have impaired decision making skills. A proxy can override their objections only with the utmost care and legal backing. Many of the rules useful for minors (subpart D) can be applied to the decisionally impaired.

