ABSTRACT. While parents have traditionally provided proxy consent for minors to participate in research, this has proven inadequate for adolescents who are mentally and emotionally capable of making their own decisions. Research has proven that even young children, and certainly most adolescents, are developmentally prepared to make such decisions for themselves. The author challenges the assumption that both consent and assent are static concepts, and proposes that a sliding scale of competence be created to ascertain the adolescent's comprehension of the proposed research by shifting the burden of proof to those who believe a particular adolescent is unable to provide informed consent.

Key words: Informed consent, clinical ethics, competence, medical decision making and research.

1. HISTORY AND DEVELOPMENT OF INFORMED CONSENT

The laudable goal of promotion of individual autonomy is often cited as the primary justification for the doctrine of informed consent. Most medical procedures and experimental research require documentation of informed consent.

Regulations established by both the U.S. Department of Health and Human Services and the Food and Drug Administration for research subjects include:

1. Invitation to the individual to become a research subject (the fact that the subject is being invited to participate in research should be clear).
2. Statement of purpose, which should include a clear indication that the study is a research study.
4. Explanation of the procedures involved in doing research, including the specific identification of any experimental procedures and an estimate of the expected duration of the research subject's participation.
5. A description of the discomforts and risks.
6. A statement of the availability of medical treatment and compen-
sation in the event that disability is incurred as a result of the research.
7. A description of any benefits to the subjects or to others that may reasonably be expected from the research.
8. A statement that describes any appropriate alternative procedures or courses of treatment to the proposed research that might be advantageous to the research subject.
9. When appropriate, a statement of any additional costs to the subject that may result from participation in research.
10. An explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights.
11. When appropriate, there should be a suggestion that the prospective subject might wish to discuss the proposed research with another.
12. A statement that participation is voluntary.
13. When appropriate, information that some information is being withheld deliberately.\(^1\)

True informed consent is viewed as a two-part active process. The first element involves informing the subject, and the second element is that of consenting, which includes assimilation of the proffered information.\(^2\)

While as long ago as the mid-eighteenth century evidence of conscription of orphans and "foundlings" for research exists,\(^3\) the historical impetus for the development of research and experimental guidelines were the egregious experiments conducted by Nazi physicians during World War II. Military judges presiding over the trial of these doctors in 1946 asked several witnesses to formulate a code of conduct for those involved in human research. The first section of what became known as the Nuremberg Code includes a mandate that "the voluntary consent of the human subject is absolutely essential."\(^4\)

In this country in an early twentieth-century case, Justice Cardozo observed in *Schloendorff v. Society of New York Hospital*, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."\(^5\) While this case examined only the issue of consent to medical treatment, consent to participate in research has developed in a parallel fashion.

One seldomly explored issue is the right of a minor to participate in research. The traditional assumption that parents will consent for their children has been challenged in recent decades\(^6\) using both deontological and utilitarian approaches. From a purely deontological, Kantian view,