In accordance with the principle of justice outlined in The Belmont Report, federal regulations and ORIC policies prohibit blanket exclusion of individuals or populations from research for reasons unrelated to the purposes of the study and not otherwise medically or scientifically justified. The inconvenience or cost of accommodating non-English speakers is not considered sufficient justification for excluding such subjects from participation in a research study.

12.6 COGNITIVELY IMPAIRED SUBJECTS

Although federal regulations do not specifically prescribe the conditions under which cognitively impaired individuals may be enrolled as subjects of research, federal guidelines do address the issues surrounding inclusion of such subjects. They state, "*(ethicists) have argued that research should involve cognitively impaired subjects only where: (1) they comprise the only appropriate subject population; (2) the research question focuses on an issue unique to subjects in this population; and (3) the research involves no more than minimal risk. (Others) argue that research involving greater than minimal risk may be acceptable where the purpose of the research is therapeutic with respect to individual subjects and where the risk is commensurate with the degree of expected benefit.*" (1993 OPRR IRB Guidebook, Chapter 6) Generally, if neither of these conditions is met, potential subjects lacking the capacity to consent should not be included in the research. However, the IRB will consider each protocol separately to determine the appropriateness of including these individuals.

The IRB determines whether or not a non-therapeutic clinical trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written consent document, or if it may be conducted in subjects with consent of a legally acceptable representative, provided the following conditions are fulfilled:

- The objectives of the clinical trial cannot be met by means of a trial in subjects who can give consent personally.
- The foreseeable risks to the subjects are minimized.
- The clinical trial is not prohibited by law.
- The opinion of the IRB is expressly sought on the inclusion of such subjects, and the written opinion covers this aspect.

Central to the review of research involving cognitively impaired subjects is the review of the process of informed consent. The description of the process of informed consent in the IRB application must clearly state the level of capacity anticipated in the population to be recruited; describe how cognition will be assessed for each potential subject; and specify what steps will be followed in the event that it is determined that a potential subject is determined to lack the capacity to consent to his/her participation. In the event that a protocol seeks to recruit individuals who may display varying levels of cognition, the IRB application should describe how the process of consent will be modified to address any fluctuations in the subject's ability to consent. Illinois State law requires the consent of a legally authorized representative of a cognitively impaired individual before the cognitively impaired individual may be included in research.