research conducted under 45 CFR 46.406 or 46.407 must also utilize a Research Subject Advocate, RSA, for each ward to be enrolled. **Please contact the IRB for guidance prior to enrolling Wards of the State on any research study regardless of the assigned risk determination. The IRB Chair is the designated Research Subject Advocate for the Institution.** If the IRB Chair is the PI for the study, the IRB Vice-Chair may be the RSA or may appoint an alternate as appropriate.

Also note that per the federal regulations, children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406 or 46.407 only if such research is:

i. Related to their status as wards; or

ii. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

12.5 NON-ENGLISH SPEAKING SUBJECTS

A sizable percentage of patients who receive their medical care at the Institution identify a language other than English as their primary language, and these non-English speakers may be eligible for participation in IRB approved research. Noting that non-English speaking people, because of their language barrier, may be more vulnerable to coercion or undue influence when approached for participation in research, the IRB acknowledges that additional provision for the protection of these potential subjects must be taken to ensure that they understand the nature of their participation in research.

Federal regulations dictate, "the information that is given to the subject or the subject's representative shall be in language understandable to the subject or the representative." (45 CFR 46.116 and 21 CFR 50.20) To fulfill this requirement, OHRP strongly encourages providing potential subjects with a full consent document written in a language understandable to them. However, for studies that are not designed to target non-English speaking individuals, this may be an unreasonable requirement. As such, the IRB may allow for the use of a "short form" written consent document in research studies that anticipate that all of or the majority of their subjects will be fluent in English, but that non-English speakers may be encountered occasionally. The "short form" consent process permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. The "short form" must state, in the subject's language, that all of the required elements of informed consent have been presented orally to the subject or his/her legal representative in a language that he/she understands.

Regardless of the method used to document non-English speakers' consent to participate in the research, the IRB's preference is that a certified interpreter be used in the verbal consent process. The IRB prefers that a certified interpreter, rather than a friend or family member of the subject be used. In the event that the subject requests to have a friend or family member serve as interpreter, care should be taken to ensure that the interpreter's relationship with the subject does not adversely impact the subject's ability to make an independent decision regarding participation. Under no circumstances should a minor be allowed to serve as interpreter.

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.