Title: SARMC Institutional Review Board: Vulnerable Populations: Decisionally Impaired and Other Potentially Vulnerable Subjects

Policy Statement: If investigators plan to include members of this vulnerable population in their research, justification is required in the application or study protocol detailing the rationale for including this population. IRB membership is required to have representation that includes the professional competency necessary to consider specific kinds of research involving decisionally impaired subjects. In cases where research involving cognitively impaired individuals is approved, the IRB may consider additional safeguards (e.g., involvement of subject advocates, independent monitoring, formal capacity assessment (performed independently and documented) as part of the research plan to protect participants. Determinations as well as any special precautions or procedures made by the IRB for research involving vulnerable populations will be documented in the meeting minutes and to the principal investigator in the initial approval letter.

Procedure:

I. Definition of Decisionally impaired

Decisionally impaired persons are individuals who have a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals who may be considered decisionally impaired, with limited decision-making ability, are individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps.

II. Research Involving Other Potentially Vulnerable Adult Subjects

Under certain circumstances, employees, students, and trainees at Saint Alphonsus as well as affiliated institutions might also be considered vulnerable subjects. The IRB shall uphold the same standards in approving research involving these groups as other vulnerable subjects research.

The context of the research is an important consideration for the IRB to consider when reviewing research that involves other potentially vulnerable subjects. For example:

A. Economically or Educationally Disadvantaged and Minority Groups

Research involving homeless persons, members of minority groups, or the economically or educationally disadvantaged pose significant challenges. Research involving certain follow-up procedures or offering significant monetary compensation may unduly influence certain types of subjects and IRB shall take such considerations into account.
B. **Educationally Disadvantaged**

Educationally disadvantaged individuals should be considered vulnerable subjects. Often these individuals may speak and understand English but are unable to read. Illiterate persons may have the informed consent read to them and may “make their mark” in a manner consistent with applicable state law to document their understanding. The signature of a witness to the consent process and the signature of the person conducting the consent interview is required. Investigators should not enroll subjects who may not truly understand what they have agreed to do.

C. **Non-English Speaking Subjects**

For research in which investigators expect to enroll non-English speaking subjects, a consent form (short form) translated into the native language of the subjects to be enrolled must be provided if an interpreter is not available. If this study population is being added to an approved research project, the consent form (short form) must be submitted with the amendment. A certified translator must perform the translation and provide proof of certification to the IRB with the translated consent form.

Any recruitment materials (flyers, radio advertisements, etc.), and any survey or questionnaires that have been translated must also be provided to the IRB when the translated consent is submitted.

The translated documents must be approved by the IRB before non-English speaking subjects can be enrolled into the study or materials distributed.

Q. **What if investigators encounter a potential subject who is Non-English-speaking, but does not have a translated consent?**

A. In some cases, a non-English speaking participant may be eligible for a study for which there is no translated consent document, and for which the study investigators could not have foreseen enrollment of a subject who speaks that language. In this case, the federal regulations allow investigators to enroll the potential subject using a "short form" consent that has been translated into the subject's native language.

The consent process must involve a translator who can verbally translate the information in the full written informed consent into the subject's native language. This translator must sign the full written informed consent as well as the short form consent to document that he or she participated in the consent process and that the subject has been fully informed regarding the study. A witness to the translation must also sign the consent form; the translator may him/herself function as the witness.
Like the translated full written consent document, the IRB must approve the translated short form consent prior to its use. However, expedited review of an amendment to approve translated short form consent is possible if the IRB has previously approved both the protocol in question and the full English-language informed consent document.

D. Non-English Reading/Illiterate
If a translator is being used to translate an informed consent form written in English, the translator must be certified.


Related Forms: Informed Consent/HIPAA Authorization Template

References:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html