iv. The IRB shall approve a written summary of what is to be said to the subject or the representative, typically the IRB approved consent English consent form serves as this summary;

v. The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form;

vi. The subject/LAR should sign the translated short form;

vii. The witness to the consent process must sign both the translated short form and the summary (English informed consent form);

viii. A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the subject/LAR. Copies of both forms must be placed in the subject's study file and medical record (as applicable).

11.4 CONSENTING SUBJECTS WHO LACK DECISIONAL CAPACITY

If an investigator wishes to enroll adults who lack decisional capacity and is unable to provide informed consent themselves, consent must be obtained from a LAR. For the purpose of this policy, "decisional capacity" is defined as "*the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment and the ability to reach and communicate an informed decision in the matter as determined by the attending physician.*" Subjects may lack decisional capacity due to a number of circumstances, such as severe psychiatric disorders, degenerative diseases affecting the brain, impaired consciousness, etc. However, investigators should note that diagnosis of mental illness or mental retardation is not an automatic bar to a determination of decisional capacity; instead, investigators should consider whether individuals with such diagnoses lack decisional capacity using the previously provided definition.

A. Assessing Capacity to Consent

All adults, regardless of condition or diagnosis of disease should be presumed competent to consent unless there is evidence of cognitive impairment or mental disability. Cognitive impairment refers to a psychological disorder, organic impairment, psychiatric disorder, a medical condition, or developmental disorder that diminishes capacity for judgment and reasoning. Subjects dependent on drugs or alcohol, subjects suffering from degenerative diseases, and terminally ill patients may also be compromised in their decision-making ability. Individuals who are incapable of providing consent cannot be enrolled in a study without the consent of a LAR.

Prior to enrollment, an investigator must assess the potential participant's capacity to consent. To do so, the investigator must determine to the best of his or her knowledge whether the subject understands the risks and benefits of the research, the therapeutic options to research, and the voluntary nature of participation. When making this determination, the investigator should ask open-ended questions of the potential subject. The IRB recommends investigators using the following questions as guidelines to assess potential subjects' capacity to consent:

- What will you be asked to do if you participate in this study?
- What are the potential risks of participating in this study?
- What are the potential benefits of participating in this study?
- How long will you be involved in the study?

- Do you know that your participation is voluntary?
- Do you understand that this is research and procedures involved in research are experimental?

The use of open-ended questions is believed to be more effective as it requires that participants vocalize their understanding of the information that has been provided to them.

B. Who May Consent for the Cognitively Impaired

The Illinois Medical Patient Rights Act (410 ILCS 50/) indicates that "no research can be conducted on a patient without prior informed consent of the patient or, if the patient is unable to consent, the patient's guardian, spouse, parent, or authorized agent." The Illinois Health Care Surrogate Act is not applicable to research.

As a general matter, if an adult lacks capacity to consent (e.g., as a result of trauma, mental retardation, some forms of mental illness, or dementia), whether temporary, progressive, or permanent, only a LAR for that adult can give consent for participation in the research, unless the requirement to obtain informed consent is waived by the IRB in accordance with the requirements at 45 CFR 46.116(e)

The LAR is defined as "the individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in research." During the consent process, the LAR should be informed that he/she will have the right to receive information on the research, as well as to withdraw consent for further participation.

If the patient regains decisional capacity during the study, he/she should be told of the LAR's decisions regarding medical treatment and enrollment on the research study. The research participant should be given information about the research and told that he/she is free to withdraw from the study if so desired. If the study subject (patient) wishes to remain on the study, he/she should sign the consent form to document this decision.

If an investigator anticipates that he/she may enroll patients who lack decisional capacity, the investigator should clarify this point in the IRB application and the protocol (when possible). In the IRB application, the PI will be asked to describe the cognitive impairment of the potential subjects, how it will be assessed, and by whom. The PI will also be asked to describe the plan for obtaining consent from the patient when he/she is capable if the cognitive impairment is temporary.

Because of the *possibility* that once a patient is capable of consenting to participate in the study but refuses to participate, the PI is required to describe the plans for what will be done with the data and specimens collected prior to the participant's dissent.

11.5 WAIVERS OF INFORMED CONSENT, PARENTAL PERMISSION, AND ASSENT

A. Waivers of Consent Requirements

At 45 CFR 46.116(e) the regulations identify when IRBs may waive or approve an alteration of informed consent/assent. The investigator may request this waiver in the research plan for research that meets four specified criteria:

i. The research involves no more than minimal risk to the subjects (this includes the minimal risk studies as defined in 21 CFR 50.3(k) or 56.102(i))