SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Research Involving Adults with Decreased Decision Making Ability	Effective: 10/25/2017
		Approved: 6/21/2017
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IRB-SOP-907		Expiration: n/a

PURPOSE

This procedure explains and establishes the investigator and IRB responsibilities for ensuring additional protections are in place when involving adults who may have decreased decision making ability. Federal Regulations (45 CFR 46.111(b), 21 CFR 56.111(b)) require IRBs give special consideration to protecting the welfare of particularly vulnerable subjects. The Ascension Wisconsin IRB considers adults with impaired decision making capacity to be a vulnerable population and must determine whether such participants should be recruited or whether additional safeguards are required to ensure the rights and welfare of subjects.

SCOPE

This SOP applies to all research conducted at Ascension Wisconsin that involves adults with impaired decision making ability, as defined in this policy, as possible human subjects. This SOP is in addition to the general requirements for obtaining and documenting informed consent outlined in *SOP: Informed Consent Process for Research* and *SOP: Documentation of Informed Consent for Research*.

DEFINITIONS

Assent: Agreement by an individual not competent to give legally valid informed consent (i.e. a child or cognitively impaired person) to participate in a research study.

Legally Authorized Representative (LAR): A person authorized either by statute or by court appointment to make decisions on behalf of another person. Under DHHS and FDA regulations a "legally authorized representative" means an individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Competence: Competence is a legal term that should not be confused with decision-making capacity. Someone who has been judged legally incompetent to handle their finances may still be able to make a meaningful choice about participating in research.

Decision Making Capacity/Capacity to Consent: Refers to a potential participant's ability to understand the information presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a meaningful decision about whether or not to participate.
Decision-making capacity is protocol-specific and situation-specific. Thus a human subject may have capacity to consent to a low-risk research protocol in usual circumstances, but not have the capacity to consent to a high-risk protocol when he or she is confused or under duress. Similarly, diminished decision-making capacity may be acute or chronic, and might worsen or improve over time.

The presence of a cognitive impairment should not lead to a presumption that a person is not capable of making a decision to participate in research.

Decreased Decision Making Ability/Decisionally Impaired: Individuals with impaired decision making ability are those having either a psychiatric or a developmental disorder that affects cognitive or emotional

functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

PROCESS

1. **Safeguards, Considerations and IRB Review**
   - **1.1** The investigator must be knowledgeable about the population and the likelihood that some or all subjects may have, or have the potential to develop, decreased decision making ability. Investigators must take special care to consider issues such as the selection of human subjects, privacy and confidentiality, coercion and undue influence, and the risks versus the benefits.
   - **1.2** The Investigators must identify this population in the IRB application and the study plan must include safeguards that are proportional to the degree of decisional impairment, the magnitude of the experimental risk, or both.
   - **1.3** The IRB must pay special attention to specific elements of the research plan when reviewing research, including the following:
     - Justification for inclusion of individuals with decisional impairment.
     - Adequate plan for assessing subjects' capacity, understanding, and informed consent or assent.
     - Provisions are made for obtaining consent from the participant or the participant's legally authorized representative.
     - Whether assent of the participants is a requirement, and, if so, whether the plan for assent is adequate.
     - The voluntary or coerced quality of the potential subject's consent, in light of the subject's relationship with the physicians conducting the study or the acute nature of the disease.
     - Whether or not additional safeguards are required such as waiting periods, assessment of capacity throughout the study, consent monitoring, etc.
   - **1.4** In order to approve research involving adults with decreased decisional ability, the IRB must determine whether or not the research plan meets the regulatory criteria for approval and if additional safeguards are in place for approximate protection of subjects. Such decisions may be based on the amount of risk involved in the research and the likelihood that participants will derive health benefits from their participation.
   - **1.5** The IRB approval notification will indicate approval for inclusion of adults with decreased decisional ability as well as any IRB requirements or protections.

2. **Determining Decision Making Ability**
   - **2.1** All adults are presumed competent to consent unless legally judged to be incompetent. Adults with impaired decision making ability are considered a vulnerable research population because their mental disability may compromise their capacity to make a reasoned decision about participation in a study.
   - **2.2** The presence of cognitive impairment does not automatically disqualify a subject from consenting/assenting to or refusing research participation. Similarly, Investigators must not interpret the potential subject's attentiveness and agreeable comments/behavior as evidence of the potential subject's competence or willingness. The critical issue is whether the cognitive impairment leads to an impaired decisional capacity.
   - **2.3** The research plan must describe how decision making ability will be assessed and by whom. Decisional ability should be assessed by someone with appropriate training and expertise, and should be evaluated on an individual basis to determine the ability of the potential subject to:
     - understand the nature of the research and of his/her participation
     - appreciate the consequences of the participation
     - show the ability to consider alternatives, including the option not to participate
     - show the ability to make a reasoned choice

2.4 Criteria for determining competence might vary according to the complexity of the study, degree of risk or discomfort presented by the research procedures and the extent to which direct benefit to the subject can be anticipated.

3. Additional Consent Considerations when Obtaining Consent

3.1 Additional considerations and requirements when obtaining consent to include an adult with decreased decision making ability as a research subject are outlined below. These are in addition to the general requirements outlined in the SOPs for obtaining and documenting informed consent.

3.2 Criteria for determining competence, the plan for assessing decision making ability and the process for reassessing decision making ability and consent/assent must be described by the Investigator in the submission.

3.3 Obtaining Consent from a Legally Authorized Representative (LAR). For subjects lacking the ability to consent, consent must be obtained by a LAR. See *SOP: Informed Consent Process for Research: Legally Authorized Representative (LAR).*

3.4 Obtaining Assent from the Subject

3.4.1 Whenever possible the investigator should consider an assent process (accompanied by consent from LAR) for adults with diminished decision making ability.

3.4.2 The assent process and/or document should be the appropriate format and level of detail for the anticipated population, whenever possible. Additionally, an affirmative assent agreement should be obtained from the subject, unless the capability of the adult is so limited that the adult cannot reasonably be consulted or the IRB determined that assent was not a requirement.

3.4.3 Assent should be documented in a similar manner to documentation of consent, see *SOP: Documentation of Consent for Research*.

REFERNCES

45 CFR 46.111(b)
21 CFR 56.111

RELATED MATERIAL

None

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	6/21/2017	New- Initial Integration Update	J. Blundon