SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Informed Consent Process for Research: Legally Authorized Representative (LAR)	Effective: 10/25/2017
		Approved: 6/21/17
Policy ID		Last Revised: n/a
IRB-SOP-904		Expiration: n/a

PURPOSE

This document establishes the process to obtain informed consent from a participant in human subject research when using a Legally Authorized Representative (LAR). These are in addition to the general requirements outlined in the SOPs for obtaining and documenting informed consent.

SCOPE

This SOP applies to all research conducted at Ascension Wisconsin where a Legally Authorized Representative will provide consent for a human research subject. 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).

Consent: Consent refers to an agreement to participate in a certain action after thoughtful consideration.

Legally Authorized Representative (LAR): A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subject research, 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.

PROCESS

1. **Obtaining Consent from a Legally Authorized Representative (LAR)**
   - **1.1** For subjects lacking the ability to consent, consent must be obtained by a LAR, if the subject lacks the capacity to consent. When Investigators identify they will enroll individuals who may have decreased or lack decisional ability, they should include in their application how they will consent these individuals.
     - **1.1.1** Whenever possible the investigator should consider an assent process (accompanied by consent from LAR) for adults with diminished decision making ability, see *SOP: Research Involving Adults with Decreased Decision Making Ability.*
   - **1.2** The Investigator should consult with the Ascension Wisconsin General Counsel when there is any question determination who can serve as an LAR.
   - **1.3** Investigators may not have anticipated the need to obtain consent from a LAR. Unplanned uses of a LAR do not require prospective IRB approval, when such uses are infrequent. However, researchers are still expected to consider the issues described.
   - **1.4** Wisconsin law prohibits a guardian or health care agent from agreeing to experimental mental health research or to psychosurgery, electroconvulsive treatment, or drastic mental health treatment procedures for an adult subject lacking capacity to consent.

2. Determining who may be an LAR

2.1 At Ascension Wisconsin, the LAR for an adult subject may be:

- A legal guardian (judicially appointed) who has clear authority to consent to participation in research, or clear authority to make health care decisions for a class of diagnostic and therapeutic decisions that are inclusive of the proposed research; or
- A person designated as a Health Care Agent with a valid and activated power of attorney for health care in accordance with State statutes.
- In the absence of both a legal guardian and a Health Care Agent, consult the IRB and/or Office of General Counsel to determine on a case-by-case basis if another individual may serve as the individual's surrogate decision maker.

3. Obtaining Consent when there is a Court Appointed Guardian

3.1.1 Wisconsin law provides that the guardian has the power to authorize the Ward's participation in an accredited or certified research project if there is no clear and convincing evidence that the ward would never have consented to research participation and the research might help the Ward, or if the research might not help the Ward, it would present no greater than minimal risk to the Ward and it might help others.

3.1.2 The guardian also has the power to authorize the Ward's participation in research that might not help the Ward but might help others even if the research involves greater than minimal risk of harm to the Ward if the guardian can establish by clear and convincing evidence that:

- the Ward would have elected to participate in such research; and
- the proposed research was reviewed and approved by the "research and human rights committee of the institution conducting the research" (IRB). The IRB is to determine in these circumstances that the research complies with the principles of the statement on the use of human subjects for research adopted by the American Association on Mental Deficiency, and with the federal regulations for research involving human subjects for federally supported projects.

4. Obtaining Consent from a Health Care Agent or Other Surrogate

4.1 When there is no Court Appointed Guardian, A Health Care Agent or other Surrogate may provide consent to research as an LAR when:

- participation of the individual in the research would accord with his/her likely preferences under the circumstances; and
- the experimental treatment presents the prospect of direct benefit to the individual, (e.g. no other comparable treatment is available or there is genuine uncertainty about the effectiveness of standard care); or
- risks to the prospective adult subject are small in relation to the potential benefit of the research to society.

REFERNCES

Wis. Stat. 54.25(2) (d) (2b & c)

RELATED MATERIAL

IRB SOP: Informed Consent for Research

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon