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: 3/18/2020
IRB-SOP-904		

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 Unless the IRB has waived the requirement to obtain consent, when research involves a population of adults that likely would present as lacking the full capacity to provide consent and the individual not objecting to participation in the research, permission must be obtained from a LAR.
   - 1.2 When Investigators identify they will enroll individuals who may have decreased or lack decisional ability, they should include in their protocol application how they will consent these individuals.
   - 1.3 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.*
   - 1.4 The Investigator should consult with the Ascension Wisconsin General Counsel when there is any question determination who can serve as an LAR.
   - 1.5 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.
   - 1.6 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.
   - 1.7 If an Ascension Wisconsin IRB is the IRB of record for study sites outside of Wisconsin, the IRB may be required to apply other laws.

2. Priority of Legally Authorized Representatives

2.1 When there is no Court Appointed Guardian, a Health Care Agent or other Surrogate may serve as legally authorized representatives and should be used in the following order of priority.

2.1.1 A health care power of attorney may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney instrument.

2.1.2 A court-appointed guardian of the person may consent to a ward's participation *in research if the court order includes the power to consent to research*.

2.1.2.1 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.

2.1.2.2 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.

2.1.2.3 A guardian of the estate or guardian ad litem cannot provide surrogate consent.

2.1.3 A power of attorney for healthcare may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney for the healthcare instrument.

2.1.4 If the potential participant has no research power of attorney, guardian, or healthcare power of attorney, then the potential participant's "next of kin" may consent on behalf of the potential participant.

2.1.4.1 "Next of kin" can provide surrogate consent in the following order: the spouse or registered domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, or a close friend of the potential participant.

2.1.4.2 Under some circumstances, an exception to the above order of priority may be appropriate. In this case, consult with the Ascension Office of General Counsel.

REFERNCES

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

RELATED MATERIAL

SOP-901 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
02	3/18/2020	Update section 2. Addition of 2.1.4. to allow "next of kin" to provide surrogate consent	J. Blundon-Kirchen