Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

LEGALLY AUTHORIZED REPRESENTATIVE - GUIDANCE

Clinical research involving human subjects is conducted under the auspices of the Prisma Health Office of Human Research Protection in compliance with federal regulations for the protection of human subjects in research. These regulations can be found at 45 CFR Part 46, as well as in Title 21 of the Code of Federal Regulations, which governs research regulated by the Food and Drug Administration.

1. **Involving Cognitively Impaired Subjects in Research**

   Research involving cognitively impaired individuals may only be approved by the IRB when the following conditions apply:

   (1) Does not present greater than minimal risk
   (2) Presents a greater probability of direct benefit to the subject than harm to the subject, or
   (3) Poses greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance to understanding or amelioration of the subject's disorder or condition.
   (4) In addition, the IRB determines the research cannot be performed solely on adults who can consent, and the focus of the research is the disorder leading to the lack of decision-making capacity.
   (5) Where the subject of the research is not directly related to the subject's lack of decision-making capacity, the investigator has presented a compelling case for including adults unable to consent.

2. **Assessment**
   a. It is the responsibility of investigators to determine and monitor the decisions-making capacity of subjects enrolled in research.
   b. If the individual is at risk for a lack of decision-making capacity, an evaluation by a qualified practitioner (who may be a qualified member of the research team) must occur.

3. **The mechanism/processes to be utilized to determine capacity/competency of a potential subject must be clearly defined in the protocol.**
   a. Ongoing assessment is required over the course of the subjects' participation in the study.
   b. In cases where, because of a known condition are risk for temporary or fluctuating capacity, the protocol must include a plan for ongoing reassessment of capacity at appropriate times during the subjects' participation in the study
   c. If decision making capacity is regained, the consent process must be repeated with the subject and the subject's consent must be obtained for continued participation in the study.

4. **Assent:**
   a. Adults with diminished decision-making capacity may retain sufficient capacity to provide meaningful assent regarding their participation in the proposed research project.
   b. The determination to allow assent of adults that have the capacity to understand and acknowledge this information must be approved by the reviewing IRB.
   c. For Assent in Children See HRPP Policies _Chapter 15_ Research Involving Children

5. **Authorized LARs**

a. If an investigator is not able to obtain informed consent from the subject, it is critical that the investigator confirm that the person providing informed consent on behalf of that person is qualified to serve as the subject's legally authorized representative under South Carolina law.
b. *South Carolina Code of Laws 44-66-30 "The Adult Health Care Consent Act."* Provides the hierarchy for determination of who may serve as a Legally Authorized representative.
c. The following list represents the general categories defined in the South Carolina Health Care Consent Act. The noted act also addresses multiple other circumstances in which an LAR may be utilized and required actions and documentation and determinations in emergency situations
    (1) Court appointed guardian
    (2) Attorney-in-fact with durable power of attorney related to health care decision
    (3) Spouse – unless legally separated, with provisions
    (4) An adult child, or majority of children if there are multiple
    (5) Parent of patient
    (6) Adult sibling, or majority of the siblings if there are multiple
    (7) Grandparent of the patient, or majority of grandparents if multiple
    (8) Other relative (by blood or marriage) believed by health care professional to have a close personal relationship
    (9) Another individual given authority to make health care decisions for the patient by another statutory provision

6. Consent of Minors in Research

a. As a general matter, when the subject is a minor (less than 18 years of age), permission (informed consent) must be obtained from the subject's parents(s) or court appointed guardian, both of whom are considered legally authorized representatives.
b. South Carolina Code of Laws Title 63_5 addresses the condition when a minor may consent with waiver of parental consent. Any research that may consider/require this waiver must consult with the HRPP staff. In consultation with Prisma Health Legal Counsel, a determination will be made.
c. Special consideration is also required if the study plan to recruit "wards of the state" as research subjects. The regulatory requirements related to consenting this population are significant beyond the scope defined in this document. A researcher will be required to present compelling evidence to conduct this research and discuss with the HRPP staff prior to commitment to such research. In consultation with Prisma Health Legal Counsel, a determination related to the feasibility of conducting this research will be made.

7. IRB Approval Required

The IRB must approve use of a Legally Authorized Representative in any proposed research. The IRB must also review and consider requirements for assent in both adult and minor subjects involved in research. IRB determinations related to this process of consent will be documented in the approval letter issued by the IRB and in IRB committee minutes.