1. PURPOSE

1.1. This policy states when a Legally Authorized Representative may provide research consent for an adult who lacks capacity to provide consent.

2. POLICY

2.1. Adults who lack capacity to provide legally effective informed consent may be unable to understand the nature and consequence of proposed health research interventions, including the subject’s diagnosis and prognosis, the burdens, benefits, and risks of any such research and the alternatives to research, and to reach an informed decision.

2.2. Studies which seek to enroll adults who may lack capacity to make an informed decision must clearly describe in the IRB application how capacity to provide informed consent will be assessed.

2.3. Adults who are determined to lack capacity to provide legally effective informed consent may be enrolled in a research study only if all of the following three conditions are met:

2.3.1. The research offers a reasonable prospect of a direct health-related benefit to the individual; OR if there is no reasonable prospect of a direct health-related benefit to the individual, then the research must pose no more than minimal risk, as determined by the IRB, and is likely to yield generalizable knowledge about the participant’s disorder or condition.

2.3.2. Informed consent for research is provided by someone who, under state or federal law, has the legal authority to make such decisions for the individual. If there is no legally authorized representative, a Substitute health care decision maker (as determined by HRP-021) may provide surrogate consent regarding the research participation.

2.3.3. The individual with cognitive impairment provides assent to participation, if capable, or does not dissent.

2.4. In all cases involving adults who lack capacity to provide legally effective informed consent and for whom a legally authorized representative is consulted as to research participation, two certifying professionals must document in the research record:

2.4.1. The basis for their determination that the individual lacks capacity to provide legally effective informed consent;

2.4.1.1. one certifying professional must examine the individual no more than one day prior to starting research procedures

2.4.2. The identity of the legally authorized representative and the rationale for the selection of the individual, which shall be documented on the Legally Authorized Representative Identification Documentation Form;

2.4.3. The process by which the individual was enrolled or declined to be enrolled in the clinical research;

2.4.4. Documentation that reassessment of consent and assent and associated documentation occurred on a regular basis during the course of the study, using a time schedule set by the investigator with the IRB’s approval

2.5. The certifying professionals must include:
2.5.1.1. one individual licensed to practice medicine in the state where the research will be taking place;

2.5.1.2. one licensed medical professional who is unaffiliated with the research.

2.6. The LAR consent and assent process for the individual unable to consent must be witnessed and documented by an individual unaffiliated with the research.