# Vulnerable Populations:

## Research Involving Persons with Impaired Decision-Making Capacity (Policy HRPP 8.2)

APRIL 2025 CONTINUING EDUCATION

# When can this type of research occur?

- Not greater than minimal risk, or
- Benefit to the subject > harm to the subject, or
- Greater than minimal risk and no direct benefit to subjects, but will yield generalizable knowledge about the subject's condition that is of importance to understanding the condition, or
- IRB determines the research cannot be performed solely on adults who can consent, and the focus of the research is the condition leading to the lack of decision-making capacity, or
- The research is not directly related to the subject's lack of decision-making capacity, the investigator has presented a compelling reason for including adults unable to consent

# Important Definitions:

- Competence
  - The capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

- Incompetence
  - Substantial impairment of cognitive functions (such as attention, comprehension, memory, and intellect), communication abilities, or other abilities that affect capacity to make and express a decision regarding participation in a study.

- Incapacity
  - A person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

- Impaired Decision-Making Capacity
  - Substantial impairment of cognitive functions (such as attention, comprehension, memory, and intellect), communication abilities, or other abilities that affect capacity to make and express a decision regarding participation in a study.

# Assessment of Cognitive Impairment and (In)Capacity:

- Determining and monitoring the decision-making capacity of subjects is the responsibility of the PI
- Methods for determination:
  - Informal assessment
    - Completed by study personnel authorized to obtain consent
    - Required for all individuals prior to Informed Consent/participating in research
  - Evaluation
    - For those identified during the informal assessment as being at significant risk for lack of decision-making
    - Completed by a qualified practitioner
      - May be a member of the research team but should not be the person obtaining consent
      - Will explain the research to the prospective participant (when feasible)
- If an individual deemed to have reduced decision-making capacity objects to participation in a study
  - Individual must be withdrawn
  - Participants will not be forced or coerced to participate in the research study

# PI Responsibilities:

- In the Protocol and eIRB application, the PI needs to describe the process of Informed Consent and include:
    - Reason(s) for including this population in the research
    - Method(s) to identify at risk individuals
    - Methods and frequency of the assessment(s)
    - Position(s) and qualifications of the practitioner(s) making the assessment(s)
    - The risk for fluctuating incapacity and the timing/methodology of re-assessment (if needed)
    - Who will be asked for consent and permission to enroll the subject if the subject is assessed as having impaired decision-making capacity
        - Provide a list and order of individuals that can serve as LAR for potential participants

- The IRB may require adjustments based on the review and determinations

# Assent:

- Adults with diminished decision-making capacity may provide assent regarding their participation
  - Absence of an objection or an inability to object should not be considered “assent”
- Assent should be sought by the person obtaining consent
- The IRB will determine whether assent required
  - If assent **is** required
    - Prior to obtaining assent, adults should be given a summary of the study
    - The IRB must determine the appropriate method, if any, for documentation based on:
      1. Length and complexity of the research
      2. The adult’s condition and psychological/emotional state
  - If assent **is not** a required
    - The investigator will explain which adults would not be asked to assent

- Investigator should also describe plans for consent for adults whose decision-making capacity is expected to improve during the study
- Proposal must be reviewed and approved by the IRB

# Legally Authorized Representative (LAR):

- An individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research
- For Non-VA research (Adult Health Care Consent Act) a LAR includes the following (in priority order)
  - Court appointed guardian
  - Attorney-in-fact with durable power of attorney related to health care decision
  - Individual authorized by another statue
  - Spouse – unless legally separated, with provisions
  - Parent or adult child
  - Adult sibling, grandparent, adult grandchild
  - Other relative (by blood or marriage) believed by health care professional, to have close personal relationship

# Legally Authorized Representative (LAR):

- For VA studies (VHA 1200.05) a LAR includes:
  - A person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC),
  - A court appointed guardian of the person and/or
  - Next-of-kin (in the following order of priority unless otherwise specified):
    - Spouse
    - Adult child (18 years of age or older)
    - Adult sibling (18 years of age or older)
    - Grandparent, or
    - Adult grandchild (18 years of age or older)
    - Close friend

# IRB Procedures:

- Use the “Special Subject Populations – Persons with Impaired Decision-Making Capacity” checklist to determine:
  - If the risk level of participation is reasonable given the intended benefit and possible alternatives
  - Appropriateness of the decision-making capacity assessment
  - Appropriateness of obtaining surrogate informed consent from a LAR
  - Whether or not the available compensation might provide undue influence, and
  - If additional protections are required
    - Presence of a subject advocate during the consenting process
    - Documented assent of the subject even when lacking decision making capacity
    - Excluding subjects without decision making capacity from selected procedures of the research
- These IRB discussions and decisions will be documented in the IRB minutes and communicated to the Principal Investigator

# Additional Review Requirements:

- Protocols conducted by MUSC and involving the VA
  - Both parties will abide by the agreements set forth in the current “Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina’s Institutional Review Boards”.
  - VA Policy places additional requirements/limitations on research with this population. Details may be found in Appendix D of VHA Handbook 1200.5.

- Protocols conducted by MUSC and sponsored by:
  - Department of Defense (DOD)
  - Department of Education
  - Department of Energy
  - Department of Justice (DOJ)/ National Institute of Justice (NIJ) and Bureau of Prisons (BOP)
  - Environmental Protection Agency (EPA)
  - Information is available on MUSC IRB Resource & Guidance Webpage: https://research.musc.edu/resources/ori/irb/resources

# What questions do you have?