

**Research Involving Persons  
with Impaired Decision  
Making Capacity**

# AAHRRP Elements

## II.4. B.

The IRB has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.

# HRPP 8.2

- Research involving cognitively impaired individuals may only be approved by the IRB when the following conditions apply:
  - Only cognitively impaired persons are suitable as research subjects and competent persons are not suitable for the proposed research. Subjects with impaired decision making capability may not be included in research because they are readily available.
  - The research entails no significant risk or if the research presents some probability of harm, there must be greater probability of direct benefit to the subjects

# Assessment

- By a qualified professional independent of the research team.
- Frequency of assessment – appropriate to population involved in a longitudinal study.
- Researcher monitors decision making capacity.
- Consideration of reconsent when subject's decision capacity changes during study

# IRB Determination

- If the risk level of participation is reasonable given the intended benefit and possible alternatives;
- The appropriateness of the decision-making capacity assessment;
- The appropriateness of obtaining surrogate informed consent from a legal representative;
- If the available compensation might provide undue influence; and
- If any additional protections are required such as the presence of a subject advocate during the consenting process, documented assent of the subject even when lacking decision making capacity, and/or excluding subjects without decision-making capacity from selected procedures of the research protocol.

# Documentation of Determination

IRB discussions and decisions will be documented in the IRB minutes and communicated to the Principal Investigator.