The University of Pittsburgh

Human Research Protection Office - **Institutional Review Board Checklist**

Research Involving Persons with Decisional Impairment

In order for the IRB to approve a study involving individuals with decisional impairment, the research must have appropriate intent as well as an acceptable level of risk.

INTENT:

- ○ The research bears a direct relationship to the decisionally impaired subject's condition
- ○ The research bears a direct relationship to the decisionally impaired subject's circumstance

LEVEL OF RISK:

- ○ The research is no greater than minimal risk to the subject
- ○ The research presents an increase over minimal risk, but offers the potential for direct individual benefit to the subject
- ○ The research presents a minor increase over minimal risk and does not have the potential for direct benefit to the subject; but the knowledge sought has direct relevance for understanding or eventually alleviating the subject's disorder or condition

ADDITIONAL SAFEGUARDS – The IRB has determined that the following are required:

- ○ Use of an independent party (not part of the study team with appropriate expertise) to assess the capacity of the potential subject
- ○ Use of standardized assessments of cognition and/or decisional capacity
- ○ Use of informational or educational techniques
- ○ Use of an independent person to monitor the consent process
- ○ Use of waiting periods to allow for additional time to consider information about the research study
- ○ Use of proxy consent
- ○ Use of assent in addition to proxy consent in order to respect the autonomy of individuals with decisional impairment

CONSENT/ASSENT ISSUES

- ○ If subjects decisional making capacity will return, provisions have been included to obtain direct consent for continued participation
- ○ For proxy consent, the investigator has appropriately indicated the order in which LARs will be approached that conforms to PA state law (See Chapter 14 of the HRPO Policy and Procedure Manual)
- ○ For subjects capable of exercising some judgment concerning the nature of the research and participation in it, the investigator should obtain the subject's assent
- ○ A signature line for a witness is included on the consent document