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
* Use of a witness – in making this determination, the IRB should indicate:
  + Whether the witness needs to be unbiased (not part of the study team or a family member)
  + Whether the witness will observe the entire consent process or just the signature

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](http://www.irb.pitt.edu/content/chapter-14-considerations-special-subject-populations) 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, if required above