Consenting Decisionally Impaired Subjects in Research Protocols
(Consenting (Adults) by Legally Authorized Representative)

Is the subject DECISIONALLY IMPAIRED?

- Yes
  - Subject identified a research proxy (when he WAS competent) & Proxy will consent

  Is the study greater than minimal risk (determined by IRB) – Section E of INSPIR

  - No
    - Is there prospect of direct benefit to individual subjects? (Sections E and I of INSPIR)
      - Yes
        - Enrollment of decisionally impaired subject NOT ALLOWED with LAR consent
      - No
        - Is it necessary to do this study on this subject /cohort of subjects to answer the study question?
          - Yes
            - Redesign the study to use a different cohort or exclude decisionally impaired subjects
          - No
            - Enrollment of decisionally impaired subject can’t be done

  - No
    - Is there NEXT OF KIN available /willing to provide consent?
      - Yes
        - Consent may be obtained from this LAR (legally authorized representative)
        - ***Provisions should be made for consenting SUBJECTS if there is a potential for them to become able to consent for themselves in the future
      - No
        - Dissent is ALWAYS honored

- No, but may become impaired during the research

A. Obtain informed consent for research from subject
B. Have subject identify a research specific proxy to give consent in the future

MEETS THE REQUIREMENTS FOR CONSENT

- No
  - Is the study greater than minimal risk (determined by IRB) – Section E of INSPIR
    - Yes
      - Can IRB grant waiver of consent (Section J4)? ** IRB can’t waive consent for FDA research except under emergency waiver
      - No
        - Is it necessary to do this study on this subject /cohort of subjects to answer the study question?
          - Yes
            - Enrollment of decisionally impaired subject NOT ALLOWED with LAR consent
          - No
            - Redesign the study to use a different cohort or exclude decisionally impaired subjects

- Yes
  - Is there NEXT OF KIN available /willing to provide consent?
    - Yes
      - Consent may be obtained from this LAR (legally authorized representative)
        - ***Provisions should be made for consenting SUBJECTS if there is a potential for them to become able to consent for themselves in the future
    - No
      - Dissent is ALWAYS honored

Revised 1/15/07 MAB    BUMC SOP for determining when LAR may be used for informed consent for research