PROCEDURE

Investigator Responsibilities:

- Submits the completed FOR200 Human Subjects Protocol (HSP) for review by the convened IRB or by the expedited procedure and specifically includes the following additional information on prospective decisionally impaired participant(s):
  - Relevancy of the research to the participant(s);
  - Cause and predicted degree of decisional incapacity and any anticipated variations in the decisional capacity of participant(s);
  - Level of research risk to the participant(s) (e.g., minimal, greater than minimal);
  - Any potential limitations of the ability of the participant(s) to provide sufficient interaction to satisfy study requirements;
  - Anticipated direct benefits to the participant(s), if any;
  - Description of plan for obtaining and documenting both the assent of the participant(s) and the permission (consent) of legally authorized representatives (LARs) or waivers of assent or permission;
    - Where it is expected enrolled participants will become decisionally impaired during the course of a study, includes provisions for identifying an LAR before the participant develops decisional impairment:
      - Justification for proposed waiver(s) of assent of participant(s) and/or permission (consent) of LAR;
        - In situations where the potential benefits of the study are such that the physicians and LAR (see POL025 UAB Policy on Definition of Legally Authorized Representative for Decisionally Impaired Adults) will enroll the patient regardless of the patient’s wishes, the participant should simply be told what is planned and should not be deceived. In such cases, the investigator should request a waiver for assent from the IRB; and
      - Any other proposed safeguards intended to protect prospective participant(s) (e.g., use of an advance directive or durable power of attorney for health care decision-making).
  - Selects the appropriate category(ies) under Special Populations on FOR200:
    - permanent impairment (e.g., mentally retarded, late stage dementia, other)
    - temporary/variable impairment (e.g., stupor or coma: traumatic, drug-induced; early Alzheimer’s disease).
• Includes with the HSP submission a copy of any interview or questionnaire that will be used to evaluate the mental status of participant(s):
  o Mini-mental status exam; or
  o Other instrument to demonstrate capacity to consent.

• Provides copies of any project-specific instruments (e.g., DVD, flip chart) used in the consenting process;

• Obtains consent, assent, or permission of LAR;

• Does not approach the decisionally impaired patient to assent to the research study until the LAR has given written permission (consent);

• Describes plan for providing information to or obtaining informed consent from participant(s) who regains decision-making capacity after having been enrolled in the study while decisionally impaired.

**OIRB Responsibilities**

The Senior Staff:

• Verifies that the HSP is complete and contains sufficient information on safeguards for decisionally impaired participants for the IRB to review;

• Reviews, specifically, informed consent documents for consent, assent, and permission of LAR, as applicable;

• Ensures the minutes reflect the deliberations of the IRB regarding any decisions rendered.

**IRB Responsibilities**

The Primary Review Team for Convened Review:

• Includes usually member(s) with knowledge or experience involving decisionally impaired individuals;

• Reviews the protocol at the time of initial and continuing review, and review of modifications;

• Using the checklist as a discussion guide, presents the protocol addressing the additional protections for decisionally impaired individuals participating in research.

The Convened IRB:

• Reviews the protocol in accordance with criteria for approval with 45 CFR 46.111, 21 CFR 56.111 if applicable, and other applicable regulations (see POL022 policy, PRO122 procedure on convened IRB review);
• When additional expertise is required, appoints a consultant to assist with review for additional safeguards in decisionally impaired participants (see POL014 policy on, PRO114 procedure for IRB use of consultants);

• Makes the following specific findings and determinations (these determinations may apply to all participants involved in the study, or on a case-by-case basis, as deemed necessary by the IRB):
  o The research is intended to study a disease or condition relevant to the vulnerable participant(s);
  o Procedures adequately account for the degree and variability of intellectual impairment;
  o Anticipated direct benefits to the participant, if any;
  o The level of risk is commensurate to the benefits; and
  o Provisions for both the assent of the participant and the permission of a legally authorized representative are adequate.

• Recommends additional safeguards to protect the rights and welfare of decisionally impaired participants, as appropriate;

  • Determines and documents that the informed consent process for consent, assent, and permission of LAR, as applicable, minimizes possibility of undue influence and coercion;
  • May determine that an enrolled decisionally impaired participant should receive information or provide informed consent during the research study if (s)he later regains decision-making capacity.

For Expedited Review an Experienced Member:

• Takes into account the decision-making capacity of the participants targeted for the study population;

• Determines that adequate provisions for obtaining consent and/or assent or waiver of consent from the participant are addressed and also how documentation of consent will be noted;

• Reviews and determines if the method of screening potential participants and controls and the factors that will be the basis for excluding potential participants from the study (e.g., mini-mental status exam or instrument to demonstrate capacity to consent) are adequate;

• May recommend additional safeguards for the decisionally impaired participants in order to secure approval of the research:

• If unable to approve the research, forwards for convened IRB review.
Approved on **October 29, 2010**, by:

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Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director