Office of Human Research Ethics Training Tips

– March 2016 Use of Legally Authorized Representative (LAR)

OHRP Guidance

In the case of an adult subject who lacks the capacity to consent, the LAR of the subject will be determined by taking the following individuals in this order of priority:

(1) **Court-appointed legal guardian**

(2) A **health care power of attorney (HCPOA)**

(3) **A durable general power of attorney**

(4) In the event that there is neither a court appointed guardian nor an agent under a durable general power of attorney or HCPOA, surrogate consent for research may be given, as long as there is no evidence to the contrary, by the **other individuals listed below**, in order of priority.

(4a) The subject's spouse;
(4b) A majority of the subject's reasonably available parents and adult children;
(4c) A majority of the subject's reasonably available adult siblings; or
(4d) Another individual with an established relationship with the subject who is acting in good faith on behalf of the subject and can reliably convey the subject's wishes.

NOTE: In the case of designations (1), (2) or (3) above, the investigator should obtain a copy of the court order, HCPOA, or durable power of attorney and should maintain the copy with the research records as documentation of the authority of the surrogate decision maker.

NOTE: *Institutional custodians or caretakers are not legally authorized representatives in the absence of a specific court appointment granting them guardianship (see above).*

ADDITIONAL NOTES:

- See SOP 32.5 for more information on IRB review of research involving decisionally impaired persons in research, and limits on this participation. For emergency research scenarios, see SOP 20.0, Emergency Use of a Test Article and SOP 21.0 Exceptions from Informed Consent Requirements for Emergency Research."
- The foregoing applies to studies in North Carolina. For studies that will be conducted in other states or countries, the investigator will be expected to determine local requirements for legally authorized representatives in consultation with the Office of University Counsel.

SOP 32.5 Decisionally impaired subjects

Decisionally impaired persons may not be enrolled in research without the prior approval of the IRB.

Other considerations when approving the inclusion of decisionally impaired subjects. Are decisionally impaired persons suitable subjects for the project? While the federal regulations do not specifically address additional protections for decisionally impaired subjects, it may be useful for the IRB to review proposed studies within the risk-benefit framework established for research involving children, as another vulnerable population lacking capacity for consent (i.e., Subpart D). Thus, enrollment of decisionally impaired subjects

- No more than minimal risk (analogous to 45 CFR 46.404); or
- Greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (~405); **or**
- A minor increase over minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge of vital importance for the understanding or amelioration of the subject's disorder or condition (~406).

2. What are the available alternatives to research participation? Is the risk-benefit balance at least as favorable as that presented by those alternatives?

3. If surrogate consent will be used, will assent of the subject also be required?

4. Are there circumstances under which a surrogate decision maker may enroll a decisionally impaired individual in the study over the individual's objection or resistance?

5. Can the consent process be structured to be appropriate and effective within the limits of the individual's decisional capacity?

6. Who will determine capacity of individual subjects to give consent? For example, the IRB might consider requiring an independent assessment by a trained professional from outside the research team (e.g., psychiatry consult service).

SOP 32.6 Research involving other potentially vulnerable adult subjects

The IRB should be sensitive to the vulnerability of subjects resulting from unique socioeconomic factors. For example, an offer of financial compensation for participation in research may be interpreted as exploitive when directed toward impoverished subjects.

SOP28.9.1 Special Issues in Consent Involving Older Children

Under North Carolina state law, a child can consent to medical treatment when he/she is emancipated or when the services are for the "prevention, diagnosis and treatment of:

(i) venereal disease and other diseases reportable under North Carolina law

(ii) pregnancy,

(iii) abuse of controlled substances or alcohol, and

(iv) emotional disturbance."

In certain cases, limited to those described below, the assent of children may, by itself, represent informed consent. Most children, however, must assent in tandem with parental permission. The special circumstances, which will be reviewed on a case-by-case basis by the IRB, include:

- Minors emancipated via court petition (In North Carolina, emancipated minors must be at least 16 years of age and must petition the courts for emancipation. Pregnancy or parenthood does not automatically emancipate a minor (See Appendix L). For children who are pregnant, assent and permission will be obtained in accordance with the regulations;
- University students under the age of 18 (See SOP 32.9.1);
- Minors who are legally married;
- Minors serving in the armed forces of the United States; or
- International subjects (investigators and IRBs should consider local laws and customs in evaluating the majority status of international subjects)

It is sufficient for researchers to use a verbal statement to confirm a child is indeed emancipated. Under North Carolina law a child is not eligible to be emancipated by a court until he or she is 16 years or older. This age restriction does not apply to married children, who are considered emancipated by virtue of being married regardless of age.