**COPIED FROM UNC HRPP SOP 28.11.2 (version dated June 18, 2012)**

**Who can act as a legally authorized representative (LAR) for a decisionally impaired research subject in North Carolina?**

As is the case for most states, North Carolina does not have State legal statutes that specifically address research enrollment. In accordance with federal regulations and guidance from the OHRP, UNC-Chapel Hill has established that the informed consent laws applicable to clinical care in North Carolina (North Carolina General Statute 90-21.13) will be followed to determine who would be considered an acceptable LAR for purposes of providing surrogate consent for decisionally impaired subjects in studies conducted in North Carolina. Although the statute is specific to medical care, it may reasonably be applied to research participation as well.

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** (except to the extent any appointed health care agent has authority, unless the health care agent’s authority has been suspended by a court order) is a court appointed guardian granted "general" guardianship or "guardian of the person" may provide surrogate consent for all activities of the individual; therefore, this guardian may provide surrogate consent for research participation of the individual.

(2) A **health care power of attorney (HCPOA)** is a health care agent pursuant to the execution of health care power of attorney document. A HCPOA document (to the extent of authority granted) grants the agent power to make health care decisions for the individual following a physician's determination that the individual lacks adequate capacity to make her/his own health care decisions. Therefore, if such a physician determination has been made, the agent under an HCPOA may provide surrogate consent for research participation; to the extent this does not contradict the written HCPOA.

(3) **A durable general power of attorney** grants the agent whatever authority is specified in the power of attorney document and is referred to as an attorney-in fact. Where the power of attorney includes a specific provision stating that it shall survive any period of incapacity or mental incompetence of the principal it is considered a “durable” power of attorney, and the person holding power of attorney may provide surrogate consent for research participation unless the research participation includes an activity expressly excluded from the power of attorney. NOTE that a general power of attorney is only valid when registered with the register of deeds in either the county named in the power of attorney or the county in which the principal resides. Before relying on the decision of a person holding a general power of attorney, investigators should require proof that the power of attorney has been registered and should examine the document to ensure that it expressly survives any period of incapacity or mental incompetence of the principal. For assistance with these determinations, please contact the Office of University Counsel.

Where there is both a valid HCPOA and a valid general power of attorney, the person holding the HCPOA has priority over the person holding the general power of attorney in making decisions regarding participation in human subjects research.

(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. When surrogate consent will be sought from one of these individuals, in the absence of a legal designation, their authority would be no broader (and may be more limited) than that of a duly appointed health care agent:

(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.

To determine the authorized representative, refer to UNC Health Care System Policy ADMIN 0019, Authorized Representatives of Patients. If there is any doubt as to which individual is the legally appropriate authorized representative for the subject, the Office of University Counsel must be contacted.

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.

Beyond the categories described above, others may not give surrogate consent for research enrollment. Institutional custodians or caretakers are not legally authorized representatives in the absence of a specific court appointment granting them guardianship (see above).

ADDITIONAL NOTES:

* While the presumption is that primary consent under these circumstances (i.e., decisional impairment) will be obtained from the LAR, there may be occasions when it is possible to seek the assent of the subjects, in addition to consent of the LAR. The IRB will determine whether assent of the participants is a requirement, and if so, whether the plan for assent is adequate.
* IRBs and investigators should seek guidance from the Office of University Counsel if there are questions about legal authorization for surrogate consent in specific situations.
* 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.