

Use of a Legally Authorized Representative in Research Involving Vulnerable Adult Participants	Effective Date	
	Revisions Date	9.16.2019

1.0 Purpose: The purpose of this standard operating practice (SOP) is to establish guidelines for the appropriate use of a legally authorized representative (LAR) to give consent for another adult to take part in human research.

2.0 Persons Affected:

- 2.1 Individuals engaged in human research activities;
- 2.2 University and Medical Center Institutional Review Board (UMCIRB) members;
- 2.3 UMCIRB office staff

3.0 SOP: At ECU, the University and Medical Center Institutional Review Board will follow North Carolina State legal statutes applicable to clinical care for purposes of providing surrogate consent for decisionally impaired adult participants in research.

4.0 Definitions:

4.1 **Decisional Impairment:** Decisionally impaired persons are those who, due to a psychiatric, organic, developmental, or other disorder or situation that affects cognitive or emotional functions, are unable to exercise independent decision making. In the absence of a specific legal or medical finding to the contrary, the individual being asked to take part in the research must be presumed to have decision making power for himself/herself and must give consent after being informed to the best ability of the research team. If there is any doubt as to an individual's capacity to consent, the investigator and the IRB should consider the need for independent assessment of capacity. If the individual does not have decisional capacity and the IRB has approved enrollment via surrogate consent, consent should be obtained from the highest available surrogate representative as described below.

4.1.2 Decisional impairment in a human research participant may be determined by a court finding of incompetence, a physician's determination, or a reasonable determination by the investigator or an independent consultant that the surrounding circumstances indicate that the individual is not able to exercise competent judgment about his/her personal risks and benefits in research participation. If a determination of decisional impairment is not confirmed by a court or physician, but only suspected, then consent should be obtained from both the individual being asked to participate in the research and the appropriate representative.

4.2 **Legally Authorized Representative (LAR):** means an individual, judicial, or other body authorized, under applicable law, to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. In the case of an adult who lacks the capacity to consent, the LAR of the potential subject will be determined by taking the following individuals in this order of priority:

4.2.1 Court-appointed legal guardian (except to the extent that 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 and may provide surrogate consent for all activities of the individual; therefore, this guardian may provide surrogate consent for research participation of the individual.

- 4.2.2 A health care power of attorney (HCPOA), e.g., a health care agent appointed pursuant to a valid health care power of attorney document.
- 4.2.3 An attorney-in-fact grants the agent whatever authority is specified in the power of attorney document.
- 4.2.4 As long as there is no evidence to the contrary, other individuals listed below, in order of priority:
 - 4.2.4.1 The individual's spouse;
 - 4.2.4.2 A majority of the individual's reasonably available parents and adult children;
 - 4.2.4.3 A majority of the individual's reasonably available adult siblings; or
 - 4.2.4.4 Another person with an established relationship with the individual who is acting in good faith on behalf of the individual and can reliably convey the individual's wishes.

4.3 In the case of designations 4.2.1, 4.2.2 or 4.2.3 above, the investigator should obtain a copy of the court order, HCPOA, or 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.

4.4 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 participants, 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.

4.5 For studies that will be conducted in other states or countries, the investigator will be expected to determine local requirements for legally authorized representatives.

5.0 Responsibilities:

5.1 **Principal Investigators** are responsible for:

5.1.1 Providing compelling, rigorous, and defensible justification to include individuals with impaired decision-making capacity as participants. These individuals should not be included in research simply because they are readily available.

5.1.2 Assessing Decision-Making Capacity. A potential research participant is generally regarded as having decision-making capacity to act on his/her own behalf if s/he demonstrates an understanding of the difference between treatment and research, demonstrates an understanding of the risks and benefits of study participation and the alternatives to study participation, and can make a decision.

5.1.2.1 In order to determine the decision-making capacity of the potential participant, a qualified health care professional must perform a formal evaluation, such as a psychiatric evaluation or a medical assessment, which considers what level of understanding is necessary for the specific research.

5.1.2.1.1 Commonly used measures to assess decision-making capacity, such as the Mini Mental Status Exam, may be helpful, but should not be the sole measure of decision-making capacity.

5.1.2.2 Certain research topics require recruiting participants who the investigator knows will have a diminished capacity to make decision either transiently or permanently.

5.1.2.3 In some cases, participants may be able to provide consent after they become cognitively or emotionally capable (e.g., after anesthesia has worn off, after a traumatic event has stabilized, etc.). This should be described by the investigator.

- 5.1.2.4 If any of the participants are expected to become decisionally-impaired during the study, the investigator must provide the IRB with details in the application on:
- 5.1.2.4.1 How decision-making capacity will be assessed;
 - 5.1.2.4.2 Who will be making the assessment (preferably someone other than research personnel); and
 - 5.1.2.4.3 How they will document the relationship of the LAR to the potential participant.
- 5.1.2.5 In other cases, there may be a predicted loss of decision making capacity of the participant, advance consent should be obtained and the participant should designate a proxy LAR during the course of the study.
- 5.1.3 Describing when a participant may be capable of assenting to participate in research even though it has been determined that a LAR should consent for the participant.
- 5.1.4 Informing the LAR of his/her role and the obligation to protect the rights and welfare of the participant by:
- 5.1.4.1 Trying to determine what the participant would decide if the participant were able to make such decisions; or,
 - 5.1.4.2 If the participant's wishes cannot be determined, what is in the participant's best interest?
 - 5.1.4.3 Providing the LAR with a copy of the consent document/HIPAA Authorization that describes the research.
 - 5.1.4.4 Including appropriate procedures for respecting a participant's wishes to dissent participation in a study even if the LAR has provided consent.
- 5.2 **UMCIRB** is responsible for:
- 5.2.1 Considering the following points as the IRB members evaluate research for which the investigator requests that the individual's legally authorized representative be permitted to act on behalf of the individual:
- 5.2.1.1 Can the information or knowledge to be gained by way of the research project be obtained in a way other than by including such decisionally impaired individuals?
 - 5.2.1.2 Enrollment of decisionally impaired individuals would generally be limited to categories of research that involve:
 - 5.4.1.2.1 no more than minimal risk; or
 - 5.4.1.2.2 greater than minimal risk but presenting the prospect of direct benefit to the individual participants; or
 - 5.4.1.2.3 a minor increase over minimal risk and no prospect of direct benefit to individual participant, but likely to yield generalizable knowledge of vital importance for the understanding or amelioration of the subject's disorder or condition.
 - 5.2.1.3 Does the research pertain specifically to the vulnerable population?
 - 5.2.1.4 Are the procedures appropriate for determining whether the subject has impaired decision-making such that the subject cannot give legally effective informed consent?
 - 5.2.1.5 Should the subject's decision-making capacity be assessed by an independent physician?
 - 5.2.1.6 Should the consent process be monitored?

5.2.1.7 Can the consent process be appropriately and effectively structured within the limits of the individual's decisional capacity?

5.2.1.8 Should a research subject advocate be involved in the consent process, initially or throughout the course of the study?

5.2.1.9 Is assent of the subject required if the subject is thought to be capable of assenting?

5.2.1.9.1 In determining whether the subject may be capable of assenting, the IRB should take into account the mental capacity and the psychological state of the subjects involved. This judgment may be made for all subjects involved in the research under a particular protocol, or for each subject, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the subjects is so limited that they cannot reasonably give their assent, the IRB may find that the assent of the subject is not a necessary condition for proceeding with the research.

5.2.1.10 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?

Revision History:

Date	Change	Reference Section(s)
11.21.2013	Updated to stand-alone document.	All
9.16.2019	Updated UMCIRB office name; moved LAR definition into Definition section; clarified PI responsibilities	Section 2.0, 4.0, 5.0

References

[NC General Statute 90-21.13](#): Informed consent to health care treatment or procedure.

FDA. Code of Federal Regulations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>

DHHS, OHRP. Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>