GUIDANCE: Investigators and Legally Authorized Representatives

Some adults are unable to give truly informed consent to participate in research and are said to suffer from diminished or impaired consent capacity. Persons with certain physical or mental conditions such as psychoses, dementias, severe strokes, severe brain injuries, or who are unconscious are common examples. It then becomes necessary to obtain permission for research participation from a second person, known as a Legally Authorized Representative or LAR. Working with LARs involves additional responsibilities for investigators. Specifically, investigators must identify who is or can be the LAR, educate the LAR about the nature of the request, and assess the competency of the LAR to give informed consent. Although a “second person” or “proxy” consent is never as desirable ethically as informed consent from the actual participant, proper identification, education, and assessment of the LAR may enhance the quality of the permission decision and the fit to the participant’s wishes. (NOTES: “Investigator” refer to any study staff who obtain consent from LARs. Also, parents are LARs for their children, but as children are, by definition, unable to consent for themselves, it is expected that parents will make their research decisions for them. Therefore, most of this guidance refers to LARs for capacity-impaired adults.

Identify the LAR

Alabama law does not specify who has such authority. The advice of the UA legal counsel is to use this list, in order of descending priority: A legally appointed guardian, authorized to give consent to medical treatment; a health care proxy/surrogate or person authorized to make medical decisions for the person in conjunction with a durable power of attorney; the person’s spouse; an adult child (if more than one, contact those who live closest first); the person’s parent; next of kin other than parent or spouse such as a sibling; and a person or agency acting in loco parentis, defined as a person or agency who voluntarily assumes responsibility for a person’s custody, care, and maintenance, in the absence of a court order formally appointing the person, such as a friend or case manager.

In some cases, as for institutionalized persons, one of the above persons may be on record as the LAR. When no such records exist, go through the above hierarchy, until a person is found who can and will serve.

Education of the LAR

It is essential that LARs understand what they are being asked to do before detailed information about the study is provided.
• Explain that (NAME OF PROSPECT) is suitable as a participant in a research study but is unable to provide truly informed consent because of his/her medical/psychological/developmental state. Tell him/her that as the guardian/spouse/parent (etc.), she/he is the person responsible for making decisions for him/her.

• State that you will provide a detailed description of the study, including the purpose, procedures, risks, benefits, and any other research-related activities the LAR would be asked to do in the study.

• Based on this information I will provide, you should make your decision based on what you believe the person would choose for him or herself and what you believe is best for that person.

• You should read the consent form, think about it, and ask questions about it. If you wish, you can have someone with you when we talk about the study, and you can talk about the study with someone you trust before you make a decision.

• It is completely up to you whether or not you want _____ to be in the study.

• If this is a MEDICAL study, refusing permission for _____ to be in the study will have no effect on his/her medical care.

Evaluation of the LAR

It cannot be assumed that LARs are automatically competent to give informed consent for the research prospect. Assess them as carefully as you would the actual prospect—are any mental or physical impediments to their decisions apparent? How well do they understand the study? Can they answer questions about it? Do they exhibit any non-verbal signs of confusion or dissent that do not go away after questions are answered? Does evidence of family disagreements or conflicts appear to be exerting an undue influence?

If you have any concern about their competence, there are two options:

• Continue the search for a suitable LAR.
• Ask a health professional to perform an assessment of the person’s ability to provide informed consent.

When consent is obtained from a LAR your signature on the consent form certifies that to the best of your knowledge, this person is able to provide legally effective consent for another person to participate in research.
Note that when possible the assent of the adult with diminished capacity to consent is also obtained. If the person refuses assent, this overrides the LAR’s consent.

The above comments are only highlights. See the policies “Protection of Pregnant Women, Fetuses, and Neonates” and “Protection of Children in Research” for detailed descriptions of assent, consent, and LARs for research with these categories of diminished consent capacity.

Again, the assent of a child old enough or healthy enough to understand the assent description is required in addition to the consent of parents or other LARs.

CONSENT FORMS FOR RESEARCH OBTAINED FROM LARS

Add the following statements to the consent form for research using LARs for adult participants as the last item before the LAR’s signature:

I understand that I am serving as the legally authorized representative for (NAME) and give permission for him/her to participate in this research study. My decision is based on what I believe that person would choose and what I believe is best for that person, based on the information I have been given.

Add “or LAR” to the signature line for the participant.

As always the research compliance specialists are happy to consult with you about LAR-related issues.