UNC School of Medicine Clinical Research Support Office

CRSO: IN THE KNOW

Identifying Legally Authorized Representatives March 2022

The requirement to obtain legally effective informed consent from participants in clinical research is one of the central protections provided under the regulations. When it has been determined that a prospective participant does not have the capacity to provide legally effective informed consent, informed consent must be obtained from a legally authorized representative (LAR). Do you know how to determine who would be considered an acceptable LAR?

At UNC-CH, North Carolina informed consent laws that apply to clinical care apply equally to clinical research. This means that when seeking to enroll a participant who lacks the capacity to provide informed consent, the following individuals may serve as an LAR in descending order of priority:

1. Court-appointed legal guardian
2. Health care power of attorney
3. Durable general power of attorney

Therefore, if the patient has both a durable general power of attorney and a health care power of attorney, only the person holding the health care power of attorney may serve as the LAR. Likewise, if the patient has either powers of attorney in place, but also a court-appointed legal guardian, only the legal guardian may serve as LAR.

If the participant does not have any of the three appointed representatives listed above, surrogate consent may be provided by the following, also in descending order of priority:

4. The participant's spouse
5. A majority of the participant's reasonably available parents and adult children
6. A majority of the participant's reasonably available adult siblings
7. 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

If an LAR is utilized, the study team must document the individual's eligibility to serve as the LAR. If a legal guardian or person holding power of attorney serves as the LAR, the study team should obtain a copy of the court order or power of attorney to maintain with the study documents. If there is any doubt as to who may serve as the LAR for a participant, the study team should contact the Office of University Counsel.

So, how do you know if a potential LAR is "reasonably available…" If the individual's relationship to the participant and their location can be readily ascertained, the person is considered reasonably available and attempts at contact should be made. An individual who is not reasonably available is one whose whereabouts are unknown (i.e., long-term estrangement), whom there is no way to contact (i.e., individuals in active military or prisoners), or who has not responded to multiple contact attempts. Not reasonably available does not mean that the individual is temporality unavailable to attend the consent discussion.

Note: In some cases, participant assent may be needed (in addition to the LAR's surrogate consent). The IRB will determine whether assent is appropriate based on the nature of the study and decision-making capacity of the prospective participants.

Note: All consent and assent procedures (including the possibility of using LARs) must be clearly described in the IRB application and approved by the IRB prior to implementation.

More Information Available

For more information about who can act as a LAR and working with LARs in clinical research, please refer to the following resources:

- UNC OHRE SOP 1101: Obtaining Informed Consent from Research Subjects (Sections 2.3 & 2.4)
- UNC OHRE SOP 1201: Vulnerable Subjects in Research (Section 2.7)
- OHRP: Informed Consent FAQs
- FDA: Draft Guidance, Informed Consent Information Sheet, Guidance for IRBs, Clinical Investigators, and Sponsors
- NIH: Research Involving Individuals with Questionable Capacity to Consent: Points to Consider

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