Use of Legally Authorized Representative (LAR)

Informed Consent Process Series

CARILION CLINIC

IRB Approval

IRB must approve enrollment of vulnerable populations and special protections may be needed for **cognitively impaired/limited decision-making capacity participants**.

Cognitively Impaired and/or Limited Decision-making Capacity=

- Unconscious/experiencing profound impairment of consciousness
- Incapable of making an informed decision due to other reasons

Note: Must have plan to assess capacity and solicit consent for continued participation for adult subjects who will or may regain decision making capacity.

Capacity for consent

- Studies must include a recruitment plan describing how capacity will be assessed when conducting research with individuals with uncertain capacity to consent
  - Plan must describe conditions indicating who will be assessed for consent and how the assessment will be performed
  - Include statement about how capacity for consent will be documented
    - Carilion Clinic documentation requirements: https://www.carilionclinic.org/adultdecisionmaking
- IRB along with the research team will review and assess the following:
  - Study risk
  - Anticipated benefits
  - Complexity of the study
  - Availability of Legally Authorized Representative(s)
  - Patient characteristics
  - Determination of additional safeguards

What is a Legally Authorized Representative (LAR)?

- “An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to subject’s participation in the procedure(s) involved in the research” (45 CFR 46.02(i) & 21 CFR 50.3 (l))
- Virginia law § 32.1-162.16 defines a legally authorized representative in the following specified order of priority for adults

Priority order for LARs (adults)

(a) Agent appointed under advance directive, as defined in § 54.1-2982

(b) legal guardian of prospective subject

(c) Spouse of prospective subject, except if divorce pending

(d) Adult child of prospective subject

(e) Parent of prospective subject when subject is an adult

(f) Adult sibling of prospective subject

(g) Any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject

Key Requirements

For a legally authorized representative to give informed consent for a prospective adult human subject to take part in human research, the prospective human subject must be found to be incapable of making an informed decision as defined in § 54.1-2982.

This means that the prospective adult subject is unable to understand the nature, extent or probable consequences of the proposed research or is unable to make a rational evaluation of the risks and benefits of alternatives to the proposed research.

Subject Incapacity Documentation

- If the prospective adult subject is unconscious or experiencing a profound impairment of consciousness due to trauma, stroke, or other acute physiological condition, a physician caring for the prospective subject must document that the prospective subject is incapable of making an informed decision for that reason

OR

- If the patient is incapable of making an informed decision due to other reasons, a physician caring for the patient as well as a second physician or clinical psychologist must document in writing that the prospective subject is incapable of making an informed decision. The second opinion shall be made by a clinician not otherwise currently involved in the treatment of the prospective subject. The Carilion consent template includes guidance on the written consent documentation requirements. For guidance on how researchers can assess a prospective subject's decision-making capacity, please see SOG 5.6.

Important restrictions

Researcher should provide the Carilion Clinic IRB with written assurance that LAR will not be allowed to consent if research…

- Contrary to the religious beliefs or basic values of the prospective subject
- Subject protests participation
- Two or more legally authorized representatives of equal decision-making priority disagree about participation

LAR may **not** consent to…

- Non-therapeutic research
  - Unless determined by IRB research will present no more than a minor increase over minimal risk

IRB Requirements

To approve a study allowing LAR to provide consent, the IRB shall consider the following considerations:

- PI plans to/has requested to enroll adults who are not capable of providing consent
- PI indicates that an appropriate Legally Authorized Representative will be asked to give consent on behalf of the incapacitated adult
- The PI indicates that all eligible subjects will require an LAR OR that some subjects may be able to provide assent or even consent for themselves
- The PI describes a plan and includes documents to assess capacity and solicit the consent for continued participation for adult subjects who will or may regain decision making capacity
- A written or script-supported consent document (or other information relevant to the research) will be provided to the research participant accompanied by a consent conversation, as applicable
- The circumstances of the consent process provide the prospective participant or the LAR sufficient opportunity to consider whether to participate
- The circumstances of the consent process minimize the possibility of coercion or undue influence
- The person communicating information to the participant or the LAR during the consent process will provide that information in language understandable to the participant or the representative

Reconsent: Decisional Capacity Changes

Regained Capacity

- If a subject regains adequate decision-making capacity, they should be asked to complete the consent process and agree to continued participant
- If at any time, the subject indicates that they do not want to continue study participation, they should be withdrawn from study

Decreased Capacity

- For subjects who develop decisional impairment after agreeing to participate, the LAR becomes responsible for making medical decisions
  - Study protocol should include a plan for LAR permission for study populations who are likely to experience decreased decisional capacity
  - LAR should be informed about the study, formal written consent from the LAR is not required because consent was initially obtained from subject
  - LAR has the authority to withdraw the subject if they conclude that it is in the subject's best interest
    - Consent form should include a statement that informs the subject about this matter and encourages them to discuss the study with their LAR

Final Note

It is the responsibility of the **principal investigator** to indicate a plan and justification for enrolling subjects who are not capable of providing legally recognized informed consent.

The IRB is responsible for approving the enrollment of individuals unable to provide consent, as well as the use of an LAR in protocol-specific circumstances.

Questions or need help?

Contact IRB office:

IRB@carilionclinic.org

References

Carilion Clinic Institutional Review Board. (2023). Standard operating guidelines for informed consent process: decision making capacity assessment for adults (SOG-5.6).

Carilion Clinic Institutional Review Board. (2023). Standard operating guidelines for informed consent process: use of legally authorized representative (SOG-5.3).

Code of Virginia § 32.1-162.16. (2023). Definition. https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/section32.1-162.16/