

	IRB SOP: Use of Legally Authorized Representative (LAR)		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-650	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

Applies to Campbell faculty, faculty advisors, students and staff conducting or overseeing human subjects research.

Purpose

This procedure outlines the process for determining the need for a Legally Authorized Representative (LAR) to consent on behalf of a subject in a research project and to define the criteria that is used to determine who meets the legal and regulatory requirements to function as a LAR.

Background

Unless the Campbell IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a Legally Authorized Representative.

Definitions

Decreased Decisional Ability: Defined as persons who evidence decreased ability to understand, communicate, reason, and/or decide. The impairment may be due to disorders of a psychiatric, organic (including those suffering from delirium or degenerative brain diseases), developmental (e.g., intellectual disability), substance misuse (e.g., those under the influence of or dependent on drugs or alcohol), or other nature that affects cognitive or emotional functions. Trauma patients, for example, may transiently lack decisional ability due to debilitating pain, taking medication to relieve debilitating pain, having strong medication side effects, or having trouble communicating.

Applicable law: Within the United States, state law dictates who may serve as a LAR from one state to the next. Outside the United States, other legal systems prevail. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Advanced Medical Directive: A document expressing a person's treatment preferences and the designation of a surrogate decision-maker if a person should become unable to make medical decisions on their own behalf.

Children: Are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Health Care Proxy: A person or organization with the power to represent or serve in the place of another; a legal document in which an individual designates another person to make health care decisions if he or she is rendered incapable of making their wishes known. The health care

	IRB SOP: Use of Legally Authorized Representative (LAR)		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-650	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

proxy has the same rights to request or refuse treatment that the individual would have if capable of making and communicating decisions.

Health Care Power of Attorney (HCPOA): Declarations by patients, made in advance of a situation in which they may be incompetent to decide about their own care, stating their treatment preferences or authorizing a third party to make decisions for them.

Principal Investigator Responsibilities and Procedures

A. Who can Consent to Research on Behalf of an Adult Subject with Decreased Decisional Ability

Unless the Campbell IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a Legally Authorized Representative.

1. When Principal Investigators (PI) identify they will enroll individuals who may have decreased or lack decisional ability, they should include in their application how they will consent these individuals, as outline in *IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*.
2. When research (involving the use of experimental treatment) is conducted in North Carolina the following individuals meet this definition:
 - a. **Court Appointed Guardian:** Determine if there is a court-appointed guardian with the power to make decisions on behalf of the patient who is incompetent to do so, always under the court's supervision. Guardianship may or may not include health care or research decisions, because legal competency is different than incapacity to give informed consent. Therefore, the presence or absence of guardianship is only a factor to be considered, and does not resolve the question of "who can give informed consent?" In these situations, the investigator should always consult with the CU General Counsel. The guardian of an adult patient should not give informed consent on behalf of the patient until the investigator has determined that the patient lacks capacity to consent.
 - b. **HCPOA:** If there is no guardian, next determine if the patient has a HCPOA to someone else under North Carolina law. This power allows the proxy to make health care decisions when the patient is incapable of communicating his/her wishes. Health care providers can presume a HCPOA was created by the individual when that individual had the capacity to make such an agreement, unless the provider has reason to know that the individual lacked capacity at the time the HCPOA was signed. One person serving as HCPOA over another cannot (under North Carolina law) consent to:
 - Admission to a mental health treatment facility,
 - Experimental mental health research,
 - Psychosurgery,

	IRB SOP: Use of Legally Authorized Representative (LAR)		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-650	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

- Electroconvulsive treatment, or
 - "Drastic mental health procedures"
- Therefore, in the absence of guidance or case law on what these terms mean, investigators should never rely on a person serving as HCPOA for any mental health research requiring clinical treatment absent consultation with the CU General Counsel.

c. **Durable Power of Attorney for healthcare**

d. **Next of Kin/Surrogate:** Finally, if there is no guardian and does not have a HCPOA or Durable Power of Attorney for healthcare, solicit consent from a next of kin (in the following order):

- The subject's spouse;
- The subject's reasonably available adult children;
- The subject's reasonably available parents;
- The subject's reasonably available adult siblings;
- The subject's reasonably available grandparents or grandchildren; or
- 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.

Do not advance to a subsequent category (e.g., adult child) unless you have established that there is no one occupying the preceding category (e.g., spouse). Document each of these determinations to justify the choice of "next of kin."

The PI cannot ask an adult child to serve as "legally authorized representative" if the subject is married. If the spouse cannot be contacted, or if the spouse declines to consent, then no one else may consent on behalf of the subject without an opinion from the Campbell University's General Counsel.

Likewise, the PI cannot ask an adult sibling to serve as "legally authorized representative" if the subject is married, or has an adult child, or a living parent. If those other parties cannot be contacted, or if they decline to consent, then the adult sibling may not consent on behalf of the subject.

If there are several persons in a single LAR category (e.g., several adult children, or several adult siblings), the PI may use his/her discretion in choosing the most appropriate "legally authorized representative." If several persons in the same LAR category (e.g., adult children) disagree about project participation, the PI would be wise to not enroll the subject or work toward consensus.

3. For all other research studies involving adults unable to consent, permission must be sought from the priority list above.

	IRB SOP: Use of Legally Authorized Representative (LAR)		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-650	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

4. Within the *Research Plan*, Investigators should describe the process they will use to determine a subject's LAR, to allow the IRB committee to review the process and its appropriateness for the project and project population.

B. Who can consent to Research on Behalf of Minors/Children

DHHS Subpart D (Additional Protections for Children Involved as Subjects in Research) applies to all research involving children. See *IRB SOP: Research Involving Minors/Children*.

When research is conducted in North Carolina all individuals under the age of 18 years are generally considered to be minors. For research conducted outside North Carolina, a determination of who is a child is to be made with consultation from the IRB Office. See *IRB SOP: Research Involving Minors/Children* for more information.

Unless the IRB has waived the requirement to obtain consent, when research involves children, consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care (for biomedical research only).

Definitions

Decreased Decisional Ability: Defined as persons who evidence decreased ability to understand, communicate, reason, and/or decide. The impairment may be due to disorders of a psychiatric, organic (including those suffering from delirium or degenerative brain diseases), developmental (e.g., intellectual disability), substance misuse (e.g., those under the influence of or dependent on drugs or alcohol), or other nature that affects cognitive or emotional functions. Trauma patients, for example, may transiently lack decisional ability due to debilitating pain, taking medication to relieve debilitating pain, having strong medication side effects, or having trouble communicating.

Applicable law: Within the United States, state law dictates who may serve as a LAR from one state to the next. Outside the United States, other legal systems prevail. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Advanced Medical Directive: A document expressing a person's treatment preferences and the designation of a surrogate decision-maker if a person should become unable to make medical decisions on their own behalf.

Children: Are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

	IRB SOP: Use of Legally Authorized Representative (LAR)		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-650	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

Health Care Proxy: A person or organization with the power to represent or serve in the place of another; a legal document in which an individual designates another person to make health care decisions if he or she is rendered incapable of making their wishes known. The health care proxy has the same rights to request or refuse treatment that the individual would have if capable of making and communicating decisions.

Health Care Power of Attorney (HCPOA): Declarations by patients, made in advance of a situation in which they may be incompetent to decide about their own care, stating their treatment preferences or authorizing a third party to make decisions for them.

References

45 CFR 46.102(i)

45 CFR 46.402(a)

21 CFR 50.3, 21 CFR 103(c)

North Carolina General Statute 90-21.13

IRB SOP: Research Involving Minors/Children

IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability