Guardianship Laws in North Carolina and Research Compliance

Federal regulations require investigators to obtain a participant's legally effective informed consent to participate in research, unless the study is minimal risk and exempt or the IRB grants a waiver of consent.

But, sometimes, individuals lack the full decision-making capacity to consent. They can still participate in research with the consent of a legally authorized representative (LAR).

In this video, we'll explore:

- The concept of decision-making capacity
- Legally effective informed consent
- The difference between an LAR and a guardian
- How guardianship laws in North Carolina intersect with human subjects research.

Understanding these laws is essential for ensuring ethical and legal compliance in IRB reviews.

What is Decisional Capacity?

There are many reasons someone may lack capacity to consent on their own behalf.

For example, children, especially young children, can express their willingness to join an activity in simple yes/no terms. But they generally lack capacity for more nuanced communication, essential to informed consent in the research setting. That's why parental permission is required except under specific circumstances.

Adults can also have limited decision-making capacity on a temporary or permanent basis due to:

- Circumstance, such as acute trauma
- The individual's physical or mental health, such as dementia, active psychosis, or mental disability

In scenarios such as these,

- What is legally authorized representation?
- Who, by law, can serve as a legally authorized representative for a research participant in North Carolina?

Legally Authorized Representatives (LARs) in Research

Federal regulations allow for a **Legally Authorized Representative (LAR)** to consent on behalf of a research participant who cannot do so themselves [45 CFR 46.102(i)].

North Carolina does not have state legal statutes that specifically address research enrollment. As a result, investigators must adhere to UNC Chapel's policy (SOP 1101) for obtaining surrogate consent for children or adults with impaired decisional capacity to participate in research. That policy requires that investigators apply consent laws applicable to clinical care to decide who can serve as an acceptable LAR.

The hierarchy for LARs for adults enrolling in research is clearly defined in the clinical care framework,

1. First, the investigator must engage the participant's court-appointed guardian, if one exists. We'll say more about guardianship later.
2. In the absence of a court-appointed guardian, the participant's health care agent, usually their Health care power of attorney (HCPOA), is next in line to serve as their LAR.
3. The participant's durable general power of attorney is third in line, if neither a guardian nor HCPOA exists. Where there is both a HCPOA and a general power of attorney, HCPOA has priority in making decisions regarding participation in research.
4. If none of these three consent options exist, the participant's spouse is next.
5. If there is no spouse, then the investigator may seek consent, in descending order of priority, from:
    - A majority of the subject's reasonably available parents and adult children;
    - A majority of the subject's reasonably available adult siblings; 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.

Whoever ultimately serves as the participant's LAR, the investigator must ensure the legal status of the LAR and document the relationship in the study record. They may rely on a court finding of incompetence or a physician's or psychologist's determination. The investigator themself may also use standardized assessments of decisional capacity such

as the MacArthur Competence Assessment Tool for Clinical Research, or they may construct a study-specific assessment of the participant's knowledge of the study.

For example, the study team may assess if the participant demonstrates understanding that:

- The activity is research and not clinical care
- That there are risks and benefits
- There are required study procedures, and possible alternatives
- Choosing not to participate will not result in penalty or loss of benefits to which they are entitled outside the research

What Is Guardianship in North Carolina?

Some people with impaired decision making may also have a guardian instead of, or in addition to, a Legally Authorized Representative. A guardian is appointed by a court to care for another called a "ward," and often has a broader scope of responsibility than an LAR. Basically, all guardians are LARs, but not all LARs are guardians.

A ward may be a minor or an adult. Children whose parents are unavailable because of death, illness, incarceration, or substance abuse may have a court-appointed guardian.

The court may also appoint a guardian for an adult because they have become mentally incapacitated or incompetent. For example, some people may be wards of the state and have a court-appointed guardian because they have an intellectual disability, mental illness, severe injury, or age-related cognitive decline.

There are three types of guardianship:

Guardian of the Person

In this type of guardianship, the guardian makes personal and medical decisions for their ward.

Guardian of the Estate

This type of guardian is appointed solely to manage their ward's financial affairs.

General Guardian

A general guardian handles all three (personal, medical, and financial decisions). Importantly, **guardianship should be a last resort**. North Carolina law requires that less

restrictive alternatives, such as supported decision-making or powers of attorney, be considered first.

Recent Legal Reforms and Ethical Implications

In 2023, North Carolina passed Senate Bill 615, reforming guardianship law to promote **supported decision-making (SDM)**. Supported decision-making is a person-centered process that allows individuals to make their own choices with the help of trusted people in their lives. For example, individuals with disabilities can choose supporters, such as family and friends, to help them understand their options, weigh consequences, and communicate their final decisions on issues like finances, healthcare, and housing.

What Does All This Mean for IRB Members?

1. Consider the necessity and reasonableness of including participants with limited decisional capacity in the proposed research.
    - Will they directly benefit from the research?
    - Are they part of the overall population that will benefit from the scientific knowledge gained from the research?
    - Is their exclusion inconsistent with the 111 criteria regarding equitable selection?

These considerations are especially important when the research poses more than minimal risk to participants.

2. Consider whether the consent and assent processes described in the IRBIS application, protocol, and Informed Consent Document are appropriate and adequate, given your understanding of the decisional capacity of the research participants.
    - Is there a good plan for assessing how well participants can express their interests and understanding of the process?
    - When appropriate, does the consent process include supportive others that participants trust?
    - When applicable, does the plan include provisions for seeking consent from the adult participant when capacity is regained, or when the minor reaches the age of majority?
    - Is assent of the participant required? The regulations leave it up to the IRB to decide when and how assent is obtained and documented, and there is no single “right way” to do so.
3. In addition to the Informed Consent Form, review other written materials, supportive documents, and visual or audio aids that the investigator proposes to use to support the consent and assent processes.

4. Use your personal experiences and expertise to weigh in on whether the study materials are appropriate for the age and decisional capacity of the participants.

Conclusion

Board members have a shared responsibility for protecting vulnerable participants who cannot fully consent on their own behalf. In that partnership, the PI is responsible for ensuring that the person serving as an LAR has the legal authority to do so.

IRB members are to determine that:

- The inclusion of the vulnerable participants in the proposed research is ethical
- The consent process is appropriate given our understanding of the participant's decisional limitations.

Remember, the IRB is responsible for deciding if assent is required and how it is obtained and documented.

Guardianship laws in North Carolina continue to evolve to better protect individual rights while ensuring ethical research practices. As IRB members, your role is critical in balancing participant protection with scientific advancement.

Thanks for watching!