

Tip Sheet 19: State and Local Law

Related Accreditation Elements: I.1.G.

Laws other than federal often influence IRB decisions, such as national, state, provincial, or local laws. The interpretation of federal regulations defining “legally authorized representative,” “child,” and “guardian” requires consideration of applicable state and local laws.

An Organization should define “legally authorized representative,” “child,” and “guardian” if it conducts or oversees research that involves these individuals. Definitions should be based on the DHHS, FDA, or both sets of regulations depending on the regulations that the Organization follows.

Policies and procedures should define which individuals meet the regulatory definitions of “legally authorized representative,” “child,” and “guardian,” or should define a process to determine which individuals meet this definition. For example, for research conducted in the state where the Organization resides, the Organization might rely on legal counsel to list the classes of individuals who meet these definitions. For other jurisdictions, the Organization might have a process, such as consultation with legal counsel to determine whether an individual or class of individuals meets these definitions or having the investigator provide a legal opinion describing which individuals or class of individuals meets these definitions.

“Legally authorized representatives” are individuals or judicial or other bodies authorized under applicable law (usually state law) to consent on behalf of a prospective participant to his or her participation in the procedures involved in the research. The purpose of this definition is to define which individuals can consent on behalf of another individual to his or her participation in research under the federal regulations. In some states, individuals who are “legal guardians,” “parents,” “surrogate decision makers,” or “proxy decision makers” as defined by state law meet the federal definitions of “legally authorized representative,” but in other states, such individuals do not meet the federal definitions of a “legally authorized representative.” The individuals

who can consent on behalf of another person vary depending on the procedures involved in the research. State law is often silent on who can consent on behalf of another person to take part in research, but can still be used to determine who is a “legally authorized representative” as defined by federal regulations. Organizations should consult with legal counsel or have a process to consult with legal counsel to determine the answer to the question: “Who under applicable law is authorized to consent on behalf of another person to undergo procedures in this research study (or class of research studies)?” The answer to that question defines who is a “legally authorized representative” for that study.

“Children” are individuals who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law (usually state law) of the jurisdiction in which the research will be conducted. The purpose of this definition is to define to whom Subpart D applies under the federal regulations. The legal age to consent to the treatments or the procedures involved in the research can depend on the legal status of the individual (e.g., emancipated or married) and can depend on the specific procedures involved (general medical care, substance abuse counseling, completion of a survey or interview, or consumption of alcohol). Organizations should consult with legal counsel or have a process to consult with legal counsel to determine the answer to the question: “Who under applicable law has reached the legal age to consent to the treatments or procedures in this research study (or class of research studies)?” The answer to that question defines the individuals who meet the federal definition of “children” for that study.

A “guardian” is an individual who is authorized under applicable law (usually state law) to consent on behalf of a child to general medical care. The purpose of this definition is to define who other than a parent can consent on behalf of a child to that child’s participation in research. Many states have laws that define a “guardian” or “legal guardian.” Some individuals designated as guardians under state law may consent on behalf of a child to general medical care and therefore also meet the federal definition of “guardian.” Other individuals designated as guardians under state law cannot consent on behalf of a child to general medical care and, therefore, do not meet the federal definitions of “guardian.” For example, the guardianship might be limited to financial affairs or physical custody. In some states, individuals may consent on behalf of a child to general medical care and meet the federal definition of “guardian” even though they are not designated as guardians under state law. Organizations should consult with legal counsel or have a process to consult with legal counsel to determine the answer to the question: “Who under applicable law is authorized to consent on behalf of this child to general medical care?” The answer to that question defines the individuals who meet the federal definition of “guardian” for that study and for that child.

Other laws may provide additional protections for participants of research and may be applicable to IRB decisions to approve research. Such laws might include those covering privacy, genetic testing, genetic information, and reporting of child, elder, or spousal abuse. Relevant law may include constitutional law, statute, regulations, and case law. Organizations should obtain legal counsel to decide what other laws are relevant. Organizations may have their own legal counsel or rely on external legal counsel. Policies and procedures should describe the application of the law in terms understandable to IRB members, IRB staff, and investigators rather than restate the law.

Other Relevant State and Local Laws:

1. Describe other laws when they are relevant to the research context, such as:
 - a. Additional protections for humans involved in research
 - b. Additional protections for vulnerable populations involved in research
 - c. Educational services
 - d. Genetics testing
 - e. HIV testing
 - f. Informed consent
 - g. Limitations of waiver of informed consent
 - h. Mandatory reporting of abuse
 - i. Mandatory disease reporting
 - j. Mental health services
 - k. Medical records
 - l. Privacy and confidentiality

Recommended Content:

1. For each law, explain how IRB members, IRB staff, and research staff should apply it.
2. If the Human Research Protection Program oversees research that involves adults unable to provide legally effective consent, policies and procedures describe the Organization's decision about or process to describe who is a "legally authorized representative" as defined by DHHS and FDA regulations when the research is conducted:
 - a. In the state where the Organization resides.
 - b. Outside the state where the Organization resides.
3. If the Human Research Protection Program oversees research that involves children as participants, policies and procedures describe the Organization's decision about or process to describe who is a "child" as defined by DHHS and FDA regulations when the research is conducted:
 - a. In the state where the Organization resides.
 - b. Outside the state where the Organization resides.
4. If the Human Research Protection Program oversees research that involves children as participants, policies and procedures describe the Organization's decision about or process to describe who is a "guardian" as defined by DHHS and FDA regulations when the research is conducted:
 - a. In the state where the Organization resides.
 - b. Outside the state where the Organization resides.