ELEMENT I.1.G.: The organization has and follows written policies and procedures that identify applicable laws in the localities where it conducts human research, takes them into account in the review and conduct of research, and resolves differences between federal or national law and local laws.

Sometimes, there are laws other than federal or national, such as state, provincial, or local, which govern the conduct of research involving human participants.

Policies and procedures should include the definitions and applicability of these laws or define a process to determine definitions and applicability, in the jurisdiction in which the organization resides, as well as in the locations where research is conducted. This would normally include obtaining legal counsel. An organization may have its own legal counsel or rely on external legal counsel. Policies and procedures should describe the application of laws so that the laws are understandable to IRB or EC members, IRB or EC staff, and researchers and research staff, rather than simply restate the law.

Independent IRBs or ECs should have a process to determine the particular international, national, and local laws that influence IRB or EC determinations within the specific locality where the research is conducted.

When research is conducted that involves children or adults who have impaired decision-making capacity, policies and procedures should define which individuals meet the legal definitions of "legally authorized representative", "child", and "guardian".

In some jurisdictions, there are other laws that provide additional protections for participants of research and are applicable to IRB or EC decisions to approve research. Such laws include privacy, genetic testing, genetic information, and reporting of child, elder, or spousal abuse.

This Element applies to research conducted in the resident country; transnational research is covered in Standard I-3.

Regulatory and guidance references

- **DHHS**: 45 CFR 46.101(e)-(f), 45 CFR 46.102(c), 45 CFR 46.402(d)-(e)
- **FDA**: 21 CFR 50.3(l), 21 CFR 50.3(o), 21 CFR 50.3(s), 21 CFR 56.103(c)
- **VA**: VHA Directive 1200.05(3)

Required written materials

1. Essential requirements:
    1. Policies and procedures describe the application of laws relevant to research involving humans as participants, when the research is conducted:
        1. In the jurisdiction where the organization resides.
        2. Outside the jurisdiction where the organization resides.
    2. Policies and procedures describe the process to resolve conflicts between federal or national law and other applicable laws.
2. When following DHHS and FDA regulations:
    1. If the organization oversees research that involves adults unable to provide legally effective consent, policies and procedures describe the organization's decision about or process to determine who is a "legally authorized representative" as defined by DHHS and FDA regulations.
    2. If the organization oversees research that involves children as participants, policies and procedures describe the organization's decision about or process to determine who is a "child" as defined by DHHS and FDA.
    3. If the organization oversees research that involves children who are wards as participants, policies and procedures describe the organization's decision about or process to determine who is a "guardian" as defined by DHHS and FDA regulations.
3. For organizations outside the US:
    1. If the organization oversees research that involves adults unable to provide legally effective consent, policies and procedures describe the organization's decision about or process to determine who is a "legally authorized representative" as defined by country law.
    2. If the organization oversees research that involves children as participants, policies and procedures describe the organization's decision about or process to determine who is a "child" as defined by defined by country law.
    3. If the organization oversees research that involves children who are wards as participants, policies and procedures describe the organization's decision about or process to determine who is a "guardian" as defined by defined by country law.

Outcomes

- The organization has access to legal counsel for assistance in applying laws to research involving human participants.
- Research complies with applicable laws relevant to research involving human participants.
- Conflicts among applicable laws are resolved.