Series 704 Differences of Laws | Institutional Review Board

The Institutional Review Board from Series 704 of Differences of Laws

I. Identifying Applicable Laws

Investigators are in the best position to learn about, disclose to the IRB, and ensure compliance with local laws in the location where the research will be carried out. Thus, identifying the laws applicable to the jurisdiction where the research will occur is the primary responsibility of the research team. That information should be shared with the IRB in the protocol submission proposing to carry out work in that jurisdiction. The Office for Human Research Protections makes available an International Compilation of Human Research Standards that are often a good starting point for researchers conducting international research. For state-specific laws outside of Utah, investigators are encouraged to locate Institutional Profile or Local Context documentation for an IRB that reviews similar research in the local jurisdiction.

II. Conflicts or Differences

From time to time, investigators and the IRB must resolve differences or conflicts between overlapping legal structures. In international research, at least the same standards of review that would apply in the U.S. must be applied elsewhere; in domestic research, different jurisdictions might have differing requirements regarding informed consent, age of majority, handling of data, and other important topics.

Where legal structures merely differ but do not conflict (i.e. one legal structure subsumes the other), following the more comprehensive requirements satisfy both jurisdictional requirements. For example, laws in Georgia and Nebraska specify that the age of majority for consenting to research practices is 19. Thus, research conducted across those and other jurisdictions that screen for participants to be aged 19 satisfies both Utah and Georgia/Nebraska's age of majority requirements.

Where legal structures conflict (i.e. monetary incentives to local leaders are necessary to conduct the research but federal policies on allowable grant expenditures would not permit such a payment), the USU Office of General Counsel will deliver to the IRB its written recommendation regarding whether and how to proceed with the proposed research.

III. Legal Compliance & Ethical Standards

Legal and ethical standards are not always in perfect alignment. A practice that is legal may not always be an ethical one. For example, while the Children's Online Privacy Protection Act permits direct solicitation of child participants aged 13 or older in the U.S., ethical standards often dictate that parental permission precede the assent of the child to formulate an ethical informed consent process. The IRB is charged with ensuring the ethical treatment of human participants in research. The Human Research Protections Office is charged with ensuring that legal requirements that protect human research participants are being met in line with applicable ethical standards. Conflicts between these two structures might occur, and consultations between the research team, the HRP staff, and the Office of General Counsel is advised prior to submitting a protocol in order to facilitate an efficient and effective review process.

IV. Researching Illegal Behavior

When researching illegal behavior, the sections above regarding conflicts or differences of laws as well as the differences between legal and ethical standards are not uncommon. Investigators are encouraged to seek out resources to ensure the protection of human research participants in the design of such projects. One example of such a resource includes

a Certificate of Confidentiality, which protects against the involuntary release of sensitive information to any party not connected to the research. Certificates of Confidentiality are issued by the National Institutes of Health and other agencies under the Department of Health and Human Services. The IRB may, in circumstances where it would protect the privacy of research participants, require a Certificate of Confidentiality as a part of the protocol review process.