

Legal Educators' Guide

Bioethics Commission Educational Materials

The Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) has developed educational materials for use in traditional and nontraditional educational settings to provide educators with contemporary examples of real-life ethical challenges addressed by a presidential commission. The materials are designed to be applicable to a wide variety of disciplines at the undergraduate, graduate, and professional levels as well as continuing education and professional training courses, graduate or professional school seminars, workplace discussions, and other settings.

The purpose of this guide is to highlight the most relevant materials for legal educators to illustrate how they might be integrated into legal education and training. This list is not exhaustive; rather, it is meant to serve as a quick reference to some of the most relevant materials.

The webinar [Multidisciplinary Implementation of Bioethics Commission Education Materials](#) demonstrates how topic-based modules can be employed in various disciplines, including the law school setting.

Federal Regulation of Human Subjects Research

Federal regulations governing federally supported human subjects research are codified by the U.S. Department of Health and Human Services in the Code of Federal Regulations at 45 C.F.R. Part 46. Subpart A of this regulation is referred to as the Common Rule and has been adopted by 18 federal agencies. Other agencies have additional regulations, for example, the U.S. Food and Drug Administration has regulations for studies it regulates which are codified at 21 C.F.R. Parts 50 and 56.

The [Informed Consent Background](#) module describes the ethical underpinnings of informed consent in human subjects research and current laws and regulations that require it, and provides the history of informed consent and how it came to be regulated in the United States. Other modules address informed consent in certain types of research that are specified by federal regulations. For example, the [Informed Consent in Gray Matters](#) module discusses research with individuals with potentially impaired consent capacity, a potentially vulnerable group that requires additional protections according to the Common Rule. In addition, the [Informed Consent in Safeguarding Children](#) module addresses medical countermeasure research with children, another vulnerable group that requires additional protections that are outlined in 45 C.F.R. Part 46 Subpart D.

The Common Rule requires that research involving vulnerable participants include additional protections. The [Vulnerable Populations Background](#) module considers various definitions of vulnerability, examples of vulnerable populations, and applicable laws, regulations, and guidance that govern how research including vulnerable individuals can proceed ethically. The [Vulnerable Populations in Safeguarding Children](#) module focuses on children as a vulnerable population and provides information on regulations for pediatric research. In addition, the [Vulnerable Populations in Gray Matters](#) module discusses potentially vulnerable groups that might participate in neuroscience and other research, such as individuals with potentially impaired consent capacity.

The [Research Design Background](#) module addresses ethical study design and relevant U.S. codes and regulations in addition to international codes and guidelines that direct the conduct of scientific research including, but not limited to, human subjects research.

Federal and State Privacy Protections

Legal scholars have explored the concept of privacy for decades, including physical privacy, decisional privacy, and electronic collection of personal information, among others. Privacy is a fundamental consideration in bioethics as well, especially in the context of human subjects research and the harms that could befall research participants from violation of their privacy.

The [Privacy Background](#) module describes the legal history of privacy, various understandings of privacy and related ethical principles, and contemporary legal notions of privacy including U.S. case law and statutory protection, the European approach to privacy, and the regulation of health privacy. It describes a constitutional right of privacy as articulated by the Supreme Court, lists legislative privacy protections, and reviews relevant case law at the state and federal levels.

The [Privacy in Privacy and Progress](#) module addresses the importance of privacy related to whole genome sequencing, and the inherent tension between protecting individuals' privacy and the supporting the progress of promising genomic research. It also considers current federal and state laws and the degree to which they protect individual genomic privacy.

Compensation or Treatment for Research-related Injury

Compensation for research-related injury ensures that individuals who are injured as a result of participating in research receive financial compensation or medical treatment (or both) as a way of making the injured research participant whole. Numerous national bodies in the United States, including several bioethics commissions, have recognized an ethical obligation to compensate injured research participants. However, the United States does not have a system to ensure that injured research participants routinely receive compensation in part because unanswered questions remain about compensating injured research participants.

The [Compensation Background](#) module explores ethical, practical, and legal considerations of various approaches to compensation for research related injury including research institution insurance, specialty courts, compensation funds, and personal insurance. The [Compensation in Moral Science](#) module addresses the ethical reasoning and current regulatory framework that relate to compensation for research related injury. The [Compensation in Safeguarding Children](#) module examines these topics as they apply to pediatric medical countermeasure research.