



User Guide for Human Subjects Researchers

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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 researchers that conduct research with human participants, or mentor or teach rising researchers, and to illustrate how they might be integrated into researcher education and training. The separate *User Guide for Researchers* provides information relevant to scientific research more generally. This list is not exhaustive; rather, it is meant to serve as a quick reference to some of the most relevant materials.

DEMOCRATIC DELIBERATION

Democratic deliberation is an inclusive method of decision making used to address open policy questions. The [Guide to Classroom Deliberation for Students and Teachers](#) provides an overview of how to conduct deliberation. A collection of [deliberative scenarios](#) is available to help students engage in deliberation using contemporary ethical questions. [Deliberative Scenario: Law Enforcement Access to a University's Genetic Database](#), with the accompanying [teacher companion](#), and [Deliberative Scenario: The Return of Genetic Research Results](#), with the accompanying [teacher companion](#), present contemporary ethical challenges involving research participants.

PRIVACY

Research participants take on risk to benefit others, including risks to their privacy, for example, by sharing personal medical information with researchers, and allowing the collection of biological samples that might provide deeply personal information. Protecting individuals' privacy is one way of minimizing potential harms to participants, such as the unauthorized disclosure of private health information.

The [Privacy Background](#) module addresses the ethical reasoning that supports privacy protection, existing legal protections, and some challenges to privacy protection. The [Privacy in Privacy and Progress](#) module addresses the importance of privacy in whole genome sequencing, and the inherent tension between protecting individuals' privacy and the supporting the progress of promising genomic research.

RESEARCH DESIGN

Scientific research is conducted for many purposes and in many disciplines. All researchers share an obligation to employ scientifically sound and ethical research design. This obligation is particularly salient in human subjects research since it would be unethical to ask participants to accept research-related risk for a study that lacks the ability to produce generalizable knowledge or potentially benefit others. Researchers use many methods to conduct scientific investigations; however, research can be considered good science only if it is conducted ethically. Developing a sound research design is an essential first step in conducting ethical research.

The [Research Design Background](#) module provides information on the essential elements of ethical research design across disciplines including categories of research, research risk, sample size, data collection and analysis, sharing of results, and validity and related concepts. In addition, it provides information on certain regulatory requirements for research including responsible conduct of research standards and human subjects research protections.

The [Research Design in Gray Matters](#) module addresses the ethical underpinnings of research design including researchers' professional ethics obligations, research ethics requirements for those conducting certain categories of research, and the obligation for all researchers to consider potential societal implications of their work.

PUBLIC AND COMMUNITY ENGAGEMENT

Public engagement enables members of the public to participate in consideration of issues of shared interest, including identifying potential impacts of research or novel technologies. Community engagement is a subset of public engagement, and focuses on the participation of communities that will be directly affected by the outcome of an action, novel technology, or research.

The [Community Engagement Background](#) module discusses various approaches to, ethical reasoning behind, and challenges to community engagement generally. The [Community Engagement in *Moral Science*](#) module builds upon the content of the Background module to address how community engagement fits into other aspects of human subjects research, such as informed consent, and considers community engagement in both domestic and international contexts, and the [Community Engagement in *Privacy and Progress*](#) module considers how community engagement applies in the context of whole genomic sequencing and data storage and usage. The [Community Engagement in *New Directions*](#) module illustrates the importance of public and community engagement for research on emerging technologies, including synthetic biology, to provide opportunities for members of the public, researchers, and policy makers to share concerns, learn from each other, and work together to support safe and productive research. The [Community Engagement in *Ethics and Ebola*](#) module provides an overview of the importance of community engagement as it relates to public health emergency planning, and ways in which community engagement can facilitate ethical research in the midst of a public health emergency.

COMPENSATION OR TREATMENT FOR RESEARCH-RELATED UNJURIES

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, and the [Compensation in *Safeguarding Children*](#) module examines the same topics as they apply to pediatric medical countermeasure research.

ETHICALLY SOUND PODCAST SERIES

The Bioethics Commission has produced a podcast series, [Ethically Sound](#), based on the 10 reports it produced during its tenure. Each podcast focuses on an ethical challenge the Bioethics Commission addressed in a specific report, and illustrates how its work influenced how these challenges were handled. The podcasts can be integrated into a lesson or training session to introduce students and trainees to a particular ethical scenario. [Ethically Sound Discussion Guide: Podcast Series Discussion Questions](#) can be used to facilitate classroom or seminar discussion.

INFORMED CONSENT

The informed consent process in research serves two primary purposes: to educate potential participants about the potential benefits and risks of participation, and to establish voluntary willingness to participate. The [Informed Consent Background](#) module describes the ethical underpinnings of informed consent in human subjects research, the history of informed consent and how it came to be regulated in the United States, and common implementation challenges for the informed consent process. Other modules provide information and analysis about informed consent processes in specific contexts such as whole genome sequencing ([Informed Consent in *Privacy and Progress*](#)), pediatric medical countermeasure research ([Informed Consent in *Safeguarding Children*](#)), research or other activities that could result in incidental and secondary findings ([Informed Consent in *Anticipate and Communicate*](#)), and neuroscience research that involves participants with potentially impaired consent capacity ([Informed Consent in *Gray Matters*](#)).

A primer, [For Researchers: Neuroscience and Consent Capacity](#), provides information for researchers to aid ethical decision making and ensure that they have considered and implemented appropriate ethical safeguards to protect participants with potentially impaired consent capacity. In addition, another primer, [For Researchers: Incidental and Secondary Findings](#), outlines how researchers should anticipate potential incidental and secondary findings that might arise in their research, develop a plan to manage such findings, and include information on the management plan in the informed consent process for potential research participants. The [For Research Participants: A Guide to Incidental Findings](#) primer provides basic information for potential research participants about incidental findings and can facilitate communication between researchers and potential participants during the informed consent process.

VULNERABLE POPULATIONS

In the human subjects research context, groups or individuals are typically considered to be vulnerable if they are unable to fully and independently protect their own interests due to intrinsic characteristics or circumstances, and must be afforded additional protections according to federal regulations and some international guidelines.

Various conceptions of vulnerability and examples of vulnerable populations are explained in the [Vulnerable Populations Background](#) module in addition to applicable regulations, guidelines, and related protections for vulnerable populations. The [Study Guide to “*Ethically Impossible*”](#) provides a historical case study based on research conducted by U.S. Public Health Service personnel in Guatemala involving the intentional exposure of vulnerable populations to sexually transmitted diseases without their consent.

The [Vulnerable Populations in *Safeguarding Children*](#) module addresses children as a vulnerable population both generally and within the context of medical countermeasure research specifically, and explores the tension between the need to protect all children to the extent possible in the event of a future bioterrorist attack, and the obligation to protect children participating in research from undue risk. 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, and the [Informed Consent in *Gray Matters*](#) module addresses how the informed consent process can be managed to encourage inclusion and protect individuals that might be potentially vulnerable.