

The Presidential Bioethics Commission: *Pedagogical Materials and Bioethics Education*

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The Presidential Commission for the Study of Bioethical Issues was created by President Obama in 2009 to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in socially and ethically responsible manners.¹ The bioethics commission is an independent and thoughtful group of experts who advises the President and, in so doing, strives to educate the nation on bioethical issues. As part of the effort to promote policies and practices ensuring ethical conduct in research, innovation, and health care delivery, the bioethics commission staff, in consultation with commission members, has used the bioethics commission reports to develop pedagogical materials for traditional and nontraditional educational settings. The goal is to use contemporary issues addressed by the bioethics commission to support teaching of bioethics ideas, prin-

ciples, and theories across the major areas of study and practice.

An overarching theme throughout the bioethics commission's reports has been the need for improvement in bioethics education for scientific and medical professionals. The commission recognizes that in this era of multidisciplinary research, where professionals from various social, biomedical, statistical, engineering, and natural sciences constitute research teams to investigate solutions to difficult health problems from diverse perspectives, there is a need to calibrate the ethical foundations established during training.

Today that need for foundational ethics encompasses more professionals than have traditionally studied basic bioethical principles. The bioethics commission has noted that those involved in the emerging field of synthetic biology, for example, come from a variety of disciplines, including engineering and computer modeling, and thus might not have had the training with ethics standards expected of scientists working in biomedical research.²

Most training in the responsible conduct of research focuses on compliance with regulations rather than addressing the ethical foundation of the regulations,³ despite the fact that funding agencies such as the National Institutes of Health define responsible conduct of research to encompass knowledge and application of ethical principles in all professional activities related to scientific research.⁴

Even among students expected to study ethics—medical students, for example—current education is not meeting expectation. A recent survey of medical students documented that many of those in their third year did not apply the language of ethics that they had learned early in medical school, even when asked to reason about situations that presented ethical challenges.⁵ Establishing the appropriate ethical foundation early in education and reinforcing it throughout a career allow professionals across disciplines to build rigorous ethics into their daily work and to anticipate problems, helping prevent ethical surprises and obstacles down the road. “Bioethics is a universally important subject, fully consonant with a liberal arts and science education, and as such it should not be taught first, let alone only, at the professional-school

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level,” the bioethics commission concluded in its third major report.⁶

In many of its ethical analyses resulting in recommendations to the President, the commission has emphasized the principle of responsible stewardship, calling for prudent vigilance in considering what we as a society can and should do in anticipation of and response to emerging technologies to be responsible stewards of the world and its safety, now and in the future. Coupled with the responsibility of individuals and institutions to use their scientific capacity in morally responsible ways, the obligation to prepare scientists of all disciplines to understand the direct and indirect impact of their work on individuals and society at large is clear. It is incumbent upon every discipline to ensure that scientists and health care providers are able to identify ethically challenging situations, to make morally sound decisions in response to these situations, and to seek and receive the support they need to do so. This is why the bioethics commission has repeatedly recommended improvements in ethics education that focus on broadening the scope of who is trained⁷ and how,⁸ as well as on increased accountability for individual investigators and practitioners.⁹ (See the online version of *HCR* and bioethics.gov for a table outlining ethics education and researcher responsibility recommendations made by the commission.)

Pedagogical Materials

In support of its recommendations for ethics education improvements, the bioethics commission has developed and posted to bioethics.gov pedagogical materials designed to reach traditional and nontraditional educators and professionals in a variety of fields. The materials are designed for use in academia—in ethics, philosophy, and applied content areas—as well as in continuing education and professional training courses, in graduate or professional school seminars, and in workplace discussion, IRB training, and other sessions. The module-based materials are designed to offer maximum flexibility for integration into existing courses or for use as stand-alone curricula. The materials are not intended to provide a comprehensive bioethics curriculum but, rather, to complement a robust teaching strategy with contemporary examples of real-life ethical challenges addressed by a presidential commission.

Judging by the number of relevant headlines, public interest in current bioethical issues is high. The objective of these resources is to capitalize on this interest and engage students and professionals through the integration of contemporary issues and case studies. When the bioethics commission publicly discussed its ethical analysis of the 1940s U.S. Public Health Service STD research in Guatemala, press coverage resulted in more than 250 original news articles in fifteen languages in more than forty countries; wire stories alone reached more than 280,000 web pages. And when the commission released its analysis of pediatric medical countermeasure research, including the possibility of pediatric anthrax vaccine research, wire coverage of the report reached more than 100,000 web pages.

The bioethics commission is an advisory body. As such, it does not make federal regulations or create laws. With that said, the commission is committed to seeing its recommendations implemented. Providing easily accessible and free materials based on the bioethics commission’s own analysis is an effort to help meet the advisors’ repeated recommendations that bioethics education should be available to a wider variety of disciplines at the undergraduate, graduate, and professional levels.

The pedagogical materials the bioethics commission now offers comprise two approaches. The first, a report-specific approach, centers on reformatting the ethical questions, considerations, theories, principles, and recommendations from a bioethics commission report into an accompanying study guide. The report study guide is designed to explore in further detail the ethical underpinnings of a topic, providing instructors and students with materials that reflect on the contents of a published bioethics commission report with the addition of reflective questions for analyses, comments by commission members or staff bioethicists, and further reading on the ethical issues likely to be revealed in discussion. The first of these report-specific materials, *A Study Guide to “Ethically Impossible” STD Research in Guatemala from 1946-1948*, examines several topics rich with potential to engage students, including vulnerable populations, secrecy, deception, scientific methods, and setting the ethical stage for such experiments. Each topic is introduced with text from the bioethics commission’s report on the experiments,¹⁰ supported with additional original documents, and followed with a comment and additional resources. This format, which varies from the temporal nature of the ethical analysis of the report itself, offers a modular approach that can be used one

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Call for Papers

Special Report on Teaching Bioethics

Deadline for submission: March 10, 2014

The *Hastings Center Report* and the Presidential Commission for the Study of Bioethical Issues are planning a special issue to address current themes in bioethics education. Guest editors include Mildred Solomon, president and CEO of The Hastings Center, and Lisa M. Lee, executive director of the Presidential Commission for the Study of Bioethical Issues.

We invite papers on the following broad topics:

- assessing the state of bioethics education (What work has been done? How do we assess? What are potential measures? What is the research agenda?);
- incorporating professional, clinical, research, and public health ethics education into medical and STEM education at secondary, undergraduate, and graduate levels;
- methods for bioethics instruction (casuistry, decision-making frameworks, pedagogical innovations, interpreting the role of history, etc.); and
- best practices in bioethics education.

We encourage manuscripts from individuals teaching in traditional and nontraditional settings with traditional as well as nontraditional students. All manuscripts will be subject to the standard peer review process by the *Hastings Center Report* editor and peer reviewers.

Submission: Manuscripts should be submitted by email. Please submit electronic copies in either *.rtf (rich text format) or *.doc (MS Word document format) to editorial@thehastingscenter.org. Specify that the manuscript is being submitted to the "Teaching Bioethics Special Report" of the *Hastings Center Report*. Name(s) and contact information for the author(s) should appear only on an accompanying cover sheet. Include a mailing address, telephone and fax numbers, and an email address. In addition to this cover sheet, all manuscripts submitted for consideration should be accompanied by an abstract of no more than 150 words, four to six key words for indexing purposes, and for each author, a signed conflict of interest form, which is available on the *Hastings Center Report's* website.

Submission guidelines, also online, give formatting instructions for essays. The deadline for submission is Monday, March 10, 2014.

topic at a time for a single in-service session or entirely to create a semester-long course from this case study.

The second, topic-oriented approach centers on single ethical considerations, theories, or principles integrating material across applicable bioethics commission reports to demonstrate ethical analyses and applications of foundational ethical principles to contemporary biomedical and scientific challenges. A single topic, such as informed consent, community engagement, or compensation for research-related injury, constitutes a module comprising a brief survey of the topic that includes definitions, explanations, ethical rationales, and an outline of current regulations, where applicable. This information provides necessary background for instructors, including those without a deep background in bioethics. Relevant bioethics commission reports are then introduced in conjunction with the brief survey of the topic to prompt questions, as well as points that might be mentioned in responses to the question, to help the instructor lead a group discussion. Related case studies and application exercises are provided to encourage deeper coverage and application of the material. As new reports are released, contemporary challenges will be woven into existing topic-oriented materials.

Applicability to Bioethics Specialty Areas

The bioethics commission's pedagogical materials address a variety of topics applicable in numerous bioethics education settings. "Bioethics" is a broad term that encompasses topics associated with ethical conduct in science, public health, and medicine. Specialty areas that have developed in recent years have created four somewhat distinct topics in the field. While there is a great degree of overlap, these four topics have separated into clinical ethics, professional ethics, public health ethics, and research ethics.

The differences in focus among these specialty areas have been strong enough to support a growing independent literature in each. In clinical, professional, and research ethics, a more limited range of opinions is considered for ethical decision-making. These fields vary from each other and from public health ethics in the question of to whom their ethical duty is owed, the process by which decisions are made, and the matter of who participates in decision-making. In clinical ethics, the duty is owed to the individual patient, and the ethical consult, which typically includes the patient, family, and clinical team, is the primary approach to decisions. In professional ethics, the duty is to the field or discipline, and decision-making involves an expert panel, with individual professionals and professional associations bearing the responsibility for this process. In research ethics, the duty is owed to the research participant, and decision-making responsibility lies with the institutional or ethics review board. In public health ethics, which has an ethical duty to the community as well as the individual, a broad range of opinions must be considered. Its decision-making process employs a public health ethics framework, with public health authorities and legislatures holding responsibility for decisions. Key

similarities across the four specialty areas include a normative approach, that is, a desire to elucidate what ought to be done; respect for those served, whether individuals, communities, or both; and the need for a decision-making process that considers questions with unclear ethical solutions by using an established framework steeped in a common set of principles that guide the decision-makers through evidence, ethical considerations, and scenario shifts to arrive at a path forward.

We developed pedagogical materials with these various bioethics specialties in mind. The materials are designed to lead students through an exploration of foundational concepts, applied to contemporary bioethical concerns. The focus is on skill building, decision-making, and incorporation of an ethical perspective into daily work, all of which apply in each specialty area. Some materials might lend themselves more to one area than another, but the intent is to develop tools that will be useful in all four areas.

All bioethics commission materials are available for free downloading at bioethics.gov. Feedback, including success stories instructors are willing to share with others, is welcomed at education@bioethics.gov.

Disclaimer

The findings and conclusions in this paper are those of the authors and do not necessarily represent the official position of the Presidential Commission for the Study of Bioethical Issues or the Department of Health and Human Services.

1. Executive Order no. 13,521, *Establishing the Presidential Commission for the Study of Bioethical Issues*, *Federal Register* 74, no. 228 (November 24, 2009): 62671.
2. Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (Washington, D.C.: PCSBI, December 2010), 134.
3. A. M. Peiffer, C. E. Hugenschmidt, and P. J. Laurienti, "Ethics in 15 Min per Week," *Science and Engineering Ethics* 17 (2011): 289-97.
4. National Institutes of Health. *Update on the Requirement for Instruction in the Responsible Conduct of Research*, Notice No.: NOT-OD-10-019, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>.
5. L. C. Kaldjian et al., "Do Medical Students Recall and Use the Language of Ethics They Are Taught Preclinically Once They Are in the Clinical Training Environment? An Empirical Study in Ethics Education," *American Journal of Bioethics Primary Research* 4, no. 2 (2013): 23-30, at 27.
6. Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subjects Research* (Washington, D.C.: PCSBI, December 2011), 73.
7. Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, 134.
8. Presidential Commission for the Study of Bioethical Issues, *Moral Science*, 72.
9. Presidential Commission for the Study of Bioethical Issues, *Moral Science*, 71; *ibid.*, *Privacy and Progress in Whole Genome Sequencing* (Washington, D.C.: PCSBI, October 2012), 82.
10. Presidential Commission for the Study of Bioethical Issues, "Ethically Impossible" *STD Research in Guatemala from 1946 to 1948* (Washington, D.C.: PCSBI, September 2011), 1-51.