

Learning How to Learn: A Review of *The Ethics and Regulation of Research with Human Subjects*

When I first started teaching medical students, I thought I had the inside track on the best source of bioethics course materials there is: legal casebooks. The casebook is a unique textbook form, composed of selections from original works (from extensive quotations to snippets), and synopses of and citations to additional materials—all woven together with extensive, elaborate, and pointed notes and questions directing students to read critically and probe further. Although all law school casebooks are eclectic, not many are exciting. However, casebooks addressing the intersections of law, science, policy, health care, and ethics have become increasingly popular in the last 30 years, and have always been remarkably interesting and thought-provoking sources of diverse, multidisciplinary information and ideas.

I always figured that my access to health law and bioethics casebooks gave me a teaching advantage in a non-law-school setting. But now the secret is out, and I'm glad, because the casebook that officially opens the door to non-law-school uses is a quintessentially good one that fills a much-needed gap. In their preface to *The Ethics and Regulation of Research with Human Subjects*, authors Carl Coleman, Jerry Menikoff, Jesse Goldner and Nancy Dubler describe the book as "a variation of the traditional law school 'casebook,' . . . designed to foster critical thinking about the subject matter involved." They have specifically designed the casebook to be accessible to students in law, medicine, nursing, public health, and health administration, recognizing that students in these fields may go on to be "tomorrow's advisers, managers, and regulators of research and research institutions." People in those roles—not to mention clinicians and researchers—need some

familiarity with a wide range of issues, literatures, and disciplinary languages pertaining to research with human subjects. This casebook is the ideal way to gain that familiarity.

No casebook can ever be exhaustive. On the first day of law school, my contracts professor famously said, "I know a lot of law—and I know where to go to find a lot more." What makes a good casebook is both what it gives you and where it points you. Research ethics and research regulation are areas in which knowing how to read, search for, compare, and keep up with information are vital. And although law students spend at least some time learning how to be intellectually adventurous without becoming an expert, health professional students often have fewer opportunities to develop and practice that approach to knowledge. This casebook shows readers how to do just that.

The book's 17 chapters are divided into three parts: 1) background and context, and 2) general considerations in reviewing research proposals, followed by 3) special considerations. The first part is a remarkably non-boring tour through the history of human subjects research and guide to the regulatory players and their roles. Famous cases and classic articles are highlighted, but a good amount of space is devoted to good new literature and less well-trodden territory, including examining sources of research funding and distinguishing research from similar activities (e.g., innovation, QI, and public health). This part closes with chapters on Institutional Review Boards (IRBs) and conflicts of interest that are surprisingly rich, considering the potential density of the topics.

Part two of the volume examines the basics of what IRBs do: risk-benefit assessment, informed consent, subject recruitment, justice, confidentiali-

ty, study monitoring, and injury compensation. Part three adds special populations considerations: children, adults without decisional capacity, prisoners, fetuses and embryos (including stem cell research and cloning), and closes with an extensive consideration of genetic research, from specimen collection to gene transfer. Finally, much like other casebooks, the volume provides not just a standard index but an extensive set of additional finding aids, as well as appendices of federal regulatory materials and important research ethics documents.

Overall, the materials provided in this casebook admirably reflect the substantial breadth and depth of scholarly and practical experience these authors have brought to bear in its assembly. This is a really user-friendly collection that will be interesting and satisfying for both teachers and students from all the areas and disciplines the authors seek to reach. The chapter on confidentiality, an important but fairly unexciting concept, provides a good example: its 30 easy-to-digest trade paperback-sized pages provide a range of discussions of confidentiality as an ethical principle; discuss state and federal law on privacy and confidentiality; examine federal research regulations and IRB guidance documents on sensitive data and medical records review; review certificates of confidentiality; and close with the complexities of HIPAA. This is by no means too much for any reader, rigor-

Carl H. Coleman, Jerry A. Menikoff, Jesse A. Goldner, Nancy Neveloff Dubler, *The Ethics and Regulation of Research with Human Subjects*, Newark, NJ: Matthew Bender & Company, Inc., LexisNexis, 2005. 746 pages, plus appendices and indices. \$48.00 softcover.



ous enough for the most serious, and most important, knits together the ethical issues and their regulatory implementation, working nicely against the misguided trend of separating “ethics” from “compliance” in human research oversight.

The only problem with a casebook in this area is not of their making: the ethics and regulation of human subjects research is a swiftly moving target, and updating this work is going to be a considerable chore. However, nobody who uses this casebook should

feel the need to sit around waiting for the update. If you’ve learned what you should by using it, you’ll know some important things, and you’ll know just how to go out and learn some more. ■