

## ***Casebook on ethical issues in international health research***

Richard Cash, Daniel Wikler, Abha Saxena & Alexander Capron, editors

Publisher: World Health Organization, Geneva, 2009; ISBN-13: 9789241547727; ISBN-10: 9241547723; 209 pages; US\$ 40 (US\$ 28 for developing countries)

This rich compilation of case studies in research ethics is designed for use by course instructors and workshop leaders. The use of case studies in workshops and formal courses is an especially valuable teaching tool, as students and workshop participants can grapple with ethical dilemmas and uncertainties in concrete situations. The editors have collected 64 case studies, based on episodes that have occurred in global health research throughout the world.

Eight chapters comprise the cases under the following titles: Defining research; Issues in study design; Harm and benefit; Voluntary informed consent; Standard of care; Obligations to participants and communities; Privacy and confidentiality; and Professional ethics. Each chapter begins with an introduction that outlines the issues and provides some guidance for the topics addressed in the cases, and ends with a brief annotated list of suggested readings. Questions for discussion follow each case. In each chapter there is cross-referencing to cases in other chapters.

Appropriately for a World Health Organization (WHO) publication, the case studies describe research that takes

place in low- and middle-income countries. In several instances, the case begins with a caveat such as: "Although this case study is based on research that took place in the 1970s, the questions that it raises remain relevant today." Readers may wonder why the editors chose cases from research that was conducted more than 30 years ago. Since the editors point out that the questions posed by each case remain relevant, it would have been better to choose more up-to-date examples. Case studies not only have to be credible as instructional materials, they also have to be timely. Knowledgeable physicians and researchers can become impatient with material they consider irrelevant to their current or future experience. Nevertheless, some cases have become classics in the field of research ethics and should, for that reason, be included in a collection such as this. An example is case 12, "Short-course AZT to prevent mother-to-child transmission of HIV", which took place in the late 1990s.

A degree of overlap in the content of different chapters is inevitable but can be confusing. An example is the inclusion of cases involving the ethics of placebo controls in chapter 2, Issues in study design, and the material covered in the introduction to chapter 5, Standard of care. In chapter 2, cases 8, 9, 10 and 12 all pose the central question of the ethics of a study design that includes a placebo control. Chapter 5 does not include any cases in which the ethical question revolves around placebo controls. However, most of the introduction to chapter 5 discusses

the paragraph in the Declaration of Helsinki that deals with placebos.

The fault in this confusion does not lie entirely with the editors of this casebook. Unfortunately, the phrase "standard of care" in the context of research is systematically ambiguous. Sometimes it refers to what the control group receives in a randomized, controlled trial (as in the placebo cases in chapter 2 and the Declaration of Helsinki discussion in the introduction to chapter 5). Sometimes the phrase refers to what participants in a prevention trial receive if they acquire the "target disease", the one the research is designed to prevent (case 32, Testing a new HIV vaccine). Sometimes it is even used in a third sense to denote ancillary medical services that may be provided to research subjects (as in case 35). Chapter 6, Obligations to participants and communities, includes a discussion of ancillary care in the introduction, and several of the cases illustrate this third sense of "standard of care". This confusion runs throughout the literature on research ethics and it would have been helpful to readers if the editors had clarified the ambiguity.

Despite these minor shortcomings, this collection of cases is a valuable resource for workshop leaders and faculty teaching courses in global health research. WHO is to be commended for its choice of world-class experts to edit this publication. ■

**review by Ruth Macklin<sup>a</sup>**

<sup>a</sup> Albert Einstein College of Medicine of Yeshiva University, 1300 Morris Park Avenue, Bronx, NY, 10463, United States of America. Correspondence to Ruth Macklin (e-mail: ruth.macklin@einstein.yu.edu).