Privacy, Confidentiality, and Health Research

The potential of the e-health revolution, increased data sharing and interlinking, research biobanks, translational research, and new techniques such as geolocation and genomics to advance human health is immense. For the full potential to be realized, though, privacy and confidentiality will have to be carefully protected. Problematically, many conventional approaches to such pivotal matters as consent, identifiability, safeguarding, security, and the international transfer of data and biospecimens are inadequate. The difficulties are aggravated in many countries by the fact that research activities are hobbled by thickets of laws, regulations, and guidance that serve neither research nor privacy well. The challenges are being heightened by the increasing use of biospecimens, and by the globalization of research in a world that has not globalized privacy protection. Drawing on examples from many developed countries and legal jurisdictions, William Lowrance critiques the issues, summarizes various ethics, policy, and legal positions (and revisions underway), describes innovative solutions, provides extensive references, and suggests ways forward.

Dr. William W. Lowrance is a consultant in health research policy and ethics, based in La Grande Motte, France. After earning a Ph.D. from The Rockefeller University in the life sciences with a concentration in organic chemistry, he shifted his attention to the social aspects of science, technology, and medicine. He has been a faculty member or fellow, teaching and conducting research on health policy, environmental policy, and risk decisionmaking, at Harvard, Stanford, and Rockefeller Universities. He has served as the Director of the Life Sciences and Public Policy Program of Rockefeller University, and as the Executive Director of the International Medical Benefit/Risk Foundation, headquartered in Geneva. His books include *Of Acceptable Risk: Science and the Determination of Safety* and *Modern Science and Human Values*. In recent years he has focused on the issues of privacy and confidentiality in health research, and he chaired the advisory committee that drafted the Ethics and Governance Framework of UK Biobank.

Cambridge Bioethics and Law

This series of books was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law's complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organizations such as the WHO and UNESCO now regularly address issues of medical law.

It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. With that in mind, we seek to address how legal analysis might have a transjurisdictional and international relevance. Organ retention, embryonic stem cell research, physician-assisted suicide and the allocation of resources to fund health care are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and health care.

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To my wonderfully supportive wife,
Catherine Couttenier-Lowrance

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Preface and acknowledgments

The potential of the e-health revolution, increased data sharing and interlinking, research biobanks, translational research, and new scientific techniques such as genomics to advance human health is immense. For the full potential to be realized, though, privacy and confidentiality will have to be carefully protected. Problematically, many current approaches to such pivotal matters as consent, identifiability, safeguarding, security, and the international transfer of data and biospecimens are inadequate. The difficulties are aggravated in many countries by the fact that research activities are hobbled by thickets of laws, regulations, guidance, and governance that serve neither research nor privacy well.

For reasons that will be discussed, much of the legal context is in flux. The EU Data Protection Directive (adopted in 1995) is being thoroughly revised, after which the Member States will revise their laws to implement the new provisions. The Council of Europe Convention 108 on Protection of Personal Data (1981) is being revised, as are the EU Clinical Trials Directive (2001), the Australian Privacy Act (1988), and the US Federal Common Rule on Protection of Human Subjects (1991). And it is inevitable that at least the research-related requirements of the Privacy Rule under the US Health Insurance Portability and Accountability Act (2002) will be revised before long. Similar changes are occurring in Asia and elsewhere as well.

This book can't resolve all of the issues; no-one has, and no book could. It is concerned not just with information recorded in the course of medical care, central though that is, but with any kind of information, from any source, that can be brought to bear as scientific evidence in health research. It uses selected examples to illustrate thematic points, not to develop comprehensive comparisons. For practical realism, it describes many of the ways research proceeds and how existing data are accessed and used and new data are generated. It is oriented to research in the developed world, and it draws on anglophone examples and sources, but most of the considerations are relevant everywhere health research is pursued.

Every effort has been made to keep the discussion concise. Complementing this, extensive references are provided, not only to support the exposition but also to help novices get their bearings and help experienced readers think about how things are done in technical specialties and ethico-legal cultures other than their own.

What this book attempts to do is identify the central issues, review them, describe ways they have been, or are being, addressed in various situations, provide resources, and suggest ways forward. Its purpose is to stimulate and inform reflection and discussion. In particular it focuses on issues, currently handled in rather different ways in different places, that must be worked on as both privacy protection and health research take on more international dimensions, and for which more internationally accepted rules and practices are urgently needed.

All web references were current as of March 2012.

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The figure, "Data flow via a research resource platform," is a modification of a figure drawn by the author for a Policy Forum article by himself and Francis S. Collins, "Identifiability in genomic research," *Science*, 317 (2007), 600.