

## ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA

This book helps readers gain an in-depth understanding of electronic health record (EHR) systems, medical big data, and the regulations that govern them. It analyzes both the shortcomings and benefits of EHR systems, exploring the law's response to the creation of these systems, highlighting gaps in the current legal framework, and developing detailed recommendations for regulatory, policy, and technological improvements. *Electronic Health Records and Medical Big Data* addresses not only privacy and security concerns but also other important challenges, such as those related to data quality and data analysis. In addition, the author formulates a large body of recommendations to improve the technology's safety, security, and efficacy for both clinical and secondary (e.g., research) uses of medical data.

Sharona Hoffman is Professor of Law and Bioethics at Case Western Reserve University. She has written over twenty articles and book chapters on EHR systems and medical big data, often with her husband, Professor of Computer Science Andy Podgurski. In 2014 she was a Distinguished Scholar in Residence at the Centers for Disease Control and Prevention's Center for Surveillance, Epidemiology and Laboratory Services. Sharona Hoffman is the author of *Aging with a Plan: How a Little Thought Today Can Vastly Improve Your Tomorrow* (2015).

## 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. Since the early 1990s, 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, and in public and political affairs. We seek to reflect the evidence that many major health-related policy debates in the United Kingdom, Europe, and the international community involve a strong medical law dimension. With this 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 healthcare 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 medicolegal 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 healthcare.

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LAW AND POLICY

**SHARONA HOFFMAN**

Case Western Reserve University School of Law



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*To my husband, Andy Podgurski*

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## Acknowledgments

I came to the topic of health information technology and the law through marriage. My husband, Andy Podgurski, is a Professor of Computer Science and Electrical Engineering at Case Western Reserve University, where I am a professor of law and bioethics and specialize in health law. Soon after we were married in 2005, we began to realize that our areas of academic interest overlapped and that what brought them together was health information technology. During many dinners and long walks, we discussed (sometimes argued about) the emerging issues raised by the advent of electronic health record (EHR) systems. We eventually wrote a large number of law review articles together, some of which form a partial basis for chapters in this book. I am deeply grateful to Andy for all he has taught me, for being a wonderful co-author, and for enriching my life in so many other ways.

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