Book Review


Privacy, Confidentiality and Health Research by William W. Lowrance has appeared like ‘manna’ from heaven. Indeed, discussions both in Europe on the proposed Directive and in the US on the Advance Notice have catapulted the topic of privacy protection in biomedical research into the policy and political arenas. Unfortunately, these proposed reforms both show signs of anaemic and ill-conceived ideas that if adopted as such will only exacerbate the current crisis of confusion, complexity and contradictions. Hence, the welcome and timely arrival of this thoughtful, well-researched and reasonable tome. Although not discussing either of these initiatives per se, this book certainly should be read before their further deliberation or adoption. I propose to highlight some of its outstanding contributions before providing a descriptive view of its contents.

First of all, the analysis of issues is objective and international (though the author admits his concentration on European and North American sources). Moreover, each chapter ends with practical and feasible reflections with the concluding chapter on ways forward being particularly insightful. Secondly, the author also provides cogent evidence, for example, as concerns the demystification of terminology whether on consent or on de-identification with masterful syntheses and clarification of the never-ending debates. On consent, he concludes that it should be ‘construed as entrusting’ (p. 86), that is more of an authorization to proceed based on a general understanding of a project’s purposes and governance. His suggested reforms include accepting broad consent, allowing exemptions when consent is impracticable, recruitment via clinical records, and reducing or waiving consent requirements for non-interventional, low risk research including research on de-identified data.

Likewise, taking issue with the ‘babel’ of terminology to describe the identifiability of person-specific data, he notes that ‘all depends on the degree of identifiability in each situation, the benefit-risk calculus and the surrounding safeguards’ (p. 109). Most importantly, he supports the policy that ‘if researchers who have access to carefully de-identified data cannot know the identities and promise to safeguard that data and not attempt to re-identify them, then the data should not be considered personally identifiable data for those researchers’ (p. 110). Hence, key-coded data used by a researcher who would not have access to the key would not be subject to personal data legislation. Caution: ‘de-identified’ is used by Lowrance to describe a process of data protection and is not necessarily synonymous with the procedures prescribed under the United States Health Insurance Portability and Accountability Act (US HIPAA) privacy rule approach (p. 99). He further suggests that a contract to not re-identify data subjects should recognize such participants as third-party beneficiaries to the agreement with legally enforceable remedies in case of negligence or deliberate breach by the researcher. He even goes so far as to suggest that these contracts, as well as their obligations and remedies, be enshrined in law (pp. 97–98).

Thirdly, mention should also be made of the chapter on genetics and genomics whose concluding reflections predict that genotyping will become routine, as will integration with electronic health records (EHRs) and other databases, thereby increasing the potential identifiability of personal data.

Finally, particular attention is paid to the often neglected subject of access, governance, data enclaves, safe harbours (‘havens’) and international data transfer. This valuable and instructive book includes chapters on data protection; biospecimens and research; confidentiality, privacy and safeguards; data protection schemes; healthcare, public health and research; consent; identifiability; genetics and genomics; safeguards and responsibilities; and data sharing, access and transfer.

This book is a must not only for bioethics and legal scholars but for policymakers and politicians. It is accessible, reader-friendly and best of all a well-thought-out tool for much needed reform.

BARTHA MARIA KNOPPERS
E-mail: bartha.knoppers@mcgill.ca

1 European Commission. Proposal for a revising the protection of individuals with regards to the processing of personal data (COM/2012/010 9 final 2). Brussels: European Commission, 2012.