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"Canadian Health Information: A Practical Legal and Risk Management Guide, 4th edition"

Noela J. Inions, Leanne E. Tran, and Lorne E. Rozovsky, 2018, 347 pages, LexisNexis, $145.00

Review by Norman M. Goldfarb

"Canadian Health Information: A Practical Legal and Risk Management Guide, 4th edition" provides a comprehensive and insightful review of the broad range of legal and practical issues that relate to health information. While the book focuses on Canadian health information, it references U.S. and E.U. legislation and regulations, such as the GDPR. Much of the material applies to the U.S. and other countries, although legal precedents and fine points will vary across borders.

While only one chapter specifically addresses clinical research, many of the chapters are relevant to clinical research, especially in areas where clinical research and clinical care overlap. The following excerpt provides an example:

> **RESEARCH ENTRIES IN HEALTH RECORDS**
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> Research participants are often drawn from the population of a health agency or provider where they are receiving established clinical treatment. Due to factors such as a particular illness, age, sex or livelihood, these individuals may be ideal participants for research projects. However, caution must be exercised in the information that is entered into individual health records to avoid confusion between clinical care, tests, treatment and research protocols, and findings. Research protocols, tests and findings may be combined with treatment records and contain medication orders, lab and imaging tests, and treatment regimes, or have separate documentation.
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> Health facilities or custodians should establish clear-cut policies and procedures for research entries. This may mean that research notations are made and stored separately and distinctly from routine clinical documentation, are made on a color-coded chart or e-file that denotes a combination of treatment and research, or are compiled in a style of writing for specifically created research entries.
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> Drawing a distinction between research and clinical care and treatment notations is important for ensuring care of the individual, integrity of the research project, and audit and reimbursement mechanisms. The chief concern is to maintain quality care. Entries in the clinical record that are confusing or irrelevant to ongoing treatment may jeopardize an individual's health. For example, many clinical trials have genetic biomarker testing. The genetic analyses usually return with a caveat that these genetic tests were conducted for research purposes, and the results should not be the basis for clinical care.
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> Routine tests and daily observations may or may not affect the outcome of a study. However, the failure to distinguish treatment from research could cast doubt upon the findings of a research project. This could happen in a drug study, for example, when a person suffers an adverse reaction to a known clinical drug on the same day when a research drug is given. Improper documentation could lead to the conclusion that the new research drug was responsible for the reaction. A carefully drafted notation indicating when the person received both drugs, the time of the reaction,

and the symptoms will all help to reduce the chance of reaching the wrong conclusion.

Difficulties could arise in financial auditing if it is subsequently determined that research drugs were included in the expenditures of health agencies. Research drugs are usually covered by research project funds and should not be a cost to the health agency. With the current schemes for insurance coverage, it may be difficult or impractical to separate one from the other. However, with ever-increasing restraints on health expenditures, this may be one area in which belt-tightening may require careful entries to distinguish clinical drug treatment from research protocols.

The book includes 19 chapters:

- Health Information and the Law
- Purposes of Health Information
- What is Health Information?
- Standards for Health Information
- Retention, Storage and Disposal
- Health Information as Evidence
- Access to Health Information
- Confidentiality, Privacy and Disclosure to Third Parties
- Digitization and Information Linkage
- Electronic Communications and Health Information
- Documenting Treatment Orders
- Documenting Health Information
- Documenting Consent
- Defamation
- Employee Health Information
- Human Research and Health Information
- Risk Management in Health Information
- Case Studies
- Prototype Policies and Procedures (including 4 sample policies and 11 sample forms)

Reviewer

Norman M. Goldfarb is Chairman of MAGI and Chief Collaboration Officer of WCG. Contact him at 1.650.465.0119 or ngoldfarb@magiworld.org.

