

## book review

*The Law of Research: a Guide*

J. Dawson and N. Pearts (eds)

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*The Law of Research: a Guide* is a major new contribution to specialist legal writing in New Zealand and the first book of its type to be published in this jurisdiction. That such a publication has been deemed necessary is a measure of the increasing complexity of the research environment and the extent to which legal issues may impact the activities of researchers and research institutions.

As the authors note, the book is the result of a major collaborative effort, principally involving members of the Faculty of Law at Otago University. However, the editors have also drawn on the expertise of lawyers from outside the Law Faculty to provide additional strength in exploring issues around the Treaty of Waitangi and intellectual property that affect research.

The purpose of the book, according to the editors, is to provide a guide to the law of research for non-lawyers. While it undoubtedly achieves this purpose, the broad scope of the book also makes it a valuable starting point for lawyers concerned to investigate legal issues associated with a particular type of research and to provide initial guidance as to relevant legislation and procedures. In accordance with its primary focus as a guide for non-lawyers, the authors have opted to provide 'plain language' explanations of developing areas of law which must be addressed by researchers before work can be commenced. As the book clearly shows, the prescriptive obligations owed to ethics committees, the requirements relating to consent and the disclosure of information and duties flowing from health and safety requirements, amongst other

obligations, represent an onerous set of responsibilities cast on researchers and their principals. Not surprisingly, the need for legal advice in this area has increased and will continue to do so as regulation increases and as economic activity drives the need for further research across a wide front.

Because the purpose of the book is principally to provide technical information, the writing is largely descriptive. In order to increase its accessibility to a lay audience, excellent use has been made throughout of flowcharts and bullet point summaries of essential information, but unencumbered by statutory references or case law citations. Such references do exist throughout the book, but have been kept to a minimum in order to make the book more accessible to those not legally trained. However, footnotes in a number of chapters do provide valuable additional information and direct readers to other sources where particular issues are discussed more thoroughly.

The book contains 18 chapters and is divided into two parts. Part I examines the public law structure of research while Part II is devoted to the private law structure of research. This seems a natural division of the material and reflects the well known distinction between private and public law which is also evident in the research environment.

The 11 chapters in Part I address a range of issues relevant to research, including academic freedom, research ethics committees, Treaty of Waitangi, environmental law, animal research, clinical trials and health and safety in research facilities. In the introductory chapter, John Dawson outlines

the scope of research law and provides a valuable overview of the diverse ways in which law and legal processes affect the conduct of research. Dawson suggests that research law may now be viewed as a distinct branch of the law, like medical law or employment law, as the full set of legal principles concerning those activities. While this book does not purport to provide such an account, it does suggest the parameters of an analysis of research law that a future, more comprehensive, publication might undertake. As Dawson notes, the field of research law now encompasses a range of dimensions which affect such matters as the regulatory devices used, the use of funding to encourage compliance with rules, the risk of multiple forms of jeopardy arising from misconduct in research and ongoing controversy about administration and accountability. One is tempted to say that the area has become a legal minefield, that is no place for the unwary or the legally unprepared.

This truth is exemplified in the discussion on research and academic freedom that constitutes the second chapter in the book. Here Michael Robertson outlines the origins and importance of the notion of academic freedom in relation to research, highlighting the dangers posed to academic freedom by private sector funding. Given the increasing alliance between private industry funding and university research, the threat to academic freedom is substantial. These risks are highlighted in the chapter with reference to a number of high profile cases in which researchers have fallen foul of their funding bodies over the issue of academic freedom, resulting in costly and stressful litigation. In addition, the growing ascendancy of the 'market' model over the epistemological model, based on a search for truth in scientific investigation, has been shown to have huge implications for intellectual property rights, as private businesses pursue profit arising from research discoveries. Robertson cautions that since the principal threat to academic freedom comes from the free choices of researchers, which are shaped by private funding and commercial concerns, the remedy lies in continued adherence by researchers to the epistemological, humanistic and democratic models of the functions a university should perform.

Because of its increasing importance in relation to research law, the issue of intellectual property (IP) is addressed as a separate chapter (16) in Part II of the book. The chapter is a useful summary of the principal forms of IP (patents, designs,

trademarks and copyright) and the legal processes for registering and protecting relevant IP interests.

IP is also discussed in chapter 4 ('The Treaty of Waitangi and Research'). In that context, a major issue, which is currently being considered by the Waitangi Tribunal, concerns an IP claim dealing with the management, use, commercialization, export and patenting of native plants and animals. The claim alleges the failure of the Crown to protect Maori interests in those indigenous resources and in all aspects of Maori cultural heritage. As the authors of that chapter note, the growing social, political and economic power of Maori within New Zealand and the increasing international recognition of indigenous people's rights, is likely to increase demands for accountability to Maori, their inclusion in research proposals and the protection of their interests in indigenous flora and fauna against the interests of biotechnology corporations, in particular in relation to genetic manipulation.

Central to the concerns of this book and an important focus of Part I is the discussion in chapter 3 on research ethics committees, contributed by John Dawson, Mary Foley and Nicola Peart. Because much of the content of the book is concerned, directly or indirectly, with health research, the role of research ethics committees is axiomatic to understanding how such research is regulated, particularly in relation to human subjects, whom it is the primary function of research ethics committees to protect. The mandatory establishment a national ethics committee pursuant to s16 of the New Zealand Public Health and Disability Act 2000 is a measure of the seriousness with which the Government views the function of ethics committees in the research environment and points to their growing influence within the regulatory framework of health research. With the ultimate enactment of the Human Assisted Reproductive Technology legislation, the specialized National Ethics Committee on Assisted Human Reproduction will have a vital role in regulating research and practice in the area, including approving and regulating applications for assisted reproductive procedures. The information provided in this book is a valuable introduction into the functions performed by ethics committees.

Other chapters in Part I dealing with research with animals, clinical trials and research on human tissue also provide a valuable descriptive account of the relevant regulatory framework for such research, highlighting the complexity of

the regulatory processes and the importance of researchers having a sound understanding of the relevant law and protocols. In each area of research, applicable legislation provides substantial penalties for non-compliance and creates an ongoing obligation upon researchers to continually reassess their practices to ensure that they conform to best practice indications of the relevant professional body. This is no less the case with animal research than in other research involving human subjects.

As noted above, the focus in Part II is upon the private law structure of research. The section begins with a chapter (12) on consent and information disclosure by Professor P.D.G. Skegg. This is, arguably, the most important chapter in the book because of the extent to which issues of informed consent and information disclosure permeate so many aspects of research. As New Zealand's leading medical law expert Professor Skegg provides a concise account of the elements of a legally valid consent, noting that the requirements of a legally effective consent vary from one area of law to another. In order to demonstrate that some areas of law impose more stringent consent requirements than others, he focuses much of the discussion on the Code of Health and Disability Services Consumers Rights (the Code of Rights) which, in New Zealand, is now the pre-eminent, legally enforceable, statement of the rights of health consumers and the obligations of health providers. However, as Professor Skegg notes, researchers who meet the requirements imposed by the Code of Rights will usually meet the requirements for informed consent of other areas of law as well, so would stand in little danger of being in breach of their legal obligations as regards the obtaining of consent. Because the requirements of consent are variable and complex, the chapter deserves careful consideration by all researchers involved in research with human subjects.

Situations in which researchers are *not* permitted to tell participants about a particular experiment ('non-disclosing research designs') and, therefore, may not obtain a truly informed consent, are the subject of the next chapter (13). The author, Selene Mize, explains that deceptive and non-disclosing research designs are most commonly found in social psychology research but are sparingly used in other disciplines. The chapter outlines the limited circumstances in which such non-disclosure may be justifiable while also highlighting the bases of potential legal challenges, including breach of

contract, infliction of emotional distress, invasion of privacy, trespass, and lack of informed consent. Obviously, the risks associated with deception and non-disclosure and failure to obtain an effective consent are grave and researchers need to be very sure of their legal position before defying such conventions in the pursuit of a particular research goal.

Some of these issues are further pursued in a later chapter (17) in Part II, dealing with liability for misconduct in research. The potential for liability arising out of research that 'goes wrong' is substantial. The authors identify the scope of liability for misconduct by researchers, including civil, professional disciplinary and criminal liability and outline the extent to which liability may be mitigated by accident compensation, to the extent that that regime is applicable.

An important remedy for misconduct in research may be disciplinary proceedings brought by an employer or associated professional body for breach of a relevant code of conduct. As the authors observe, most research institutions have policies or guidelines setting out research standards and defining relevant misconduct. Because disciplinary proceedings may be brought at the discretion of an employer and may involve a range of penalties of varying degrees of seriousness, including dismissal, employment law is also implicated and may need to be separately addressed. Because of the importance of employment law generally within the research environment, the subject is separately considered in chapter 15, written by Paul Roth. The chapter constitutes a useful summary of the essential elements of employment law applicable to those involved in research.

The remaining chapters in this Part (14 and 18) deal respectively with children as research participants and research contracts. The chapter dealing with children as research participants is important because of the unique considerations attaching to children as research subjects. Their inherent vulnerability and often presumed incompetence to either consent or refuse consent to medical procedures may, in the past, have exposed some competent children to unwanted interventions that were not clearly in their best interests. However, as the authors note, children's actual capacity to consent to medical interventions is not primarily a feature of their age so much as their ability to understand information provided and make a choice. According to this approach, many children below the age of 16, when capacity to make decisions

affecting a range of activities is generally presumed, may actually have relevant capacity, regardless of guardians' or proxies' adverse views.

These realities need to be carefully considered by researchers in deciding whether a child lacks competence or whether a proxy consent may be necessary. The authors make the useful suggestion that because of their special vulnerability and particular needs, research projects involving them should be designed or supervised by people experienced in dealing with children. This would also assume a greater understanding of the quite complex issues around children's consent.

The concluding chapter 18 deals with research contracts. The accurate formulation of such contracts is clearly axiomatic to the concerns this book addresses and, therefore, provides an important concluding focus to this book. The authors, John Dawson and Catherine Dunckley, examine the different types of research contract, the nature of the contracting process and the essence of contract law before briefly discussing the importance of intellectual property arrangements and confidentiality.

The book concludes with a comprehensive 20 page index which, in a book of this type, is a significant aid to accessing needed information. Discussions on common topics appearing in a number of chapters are cross referenced, assisting the use

of the text as a ready reference for basic information on a particular subject.

The editors are to be commended for their efforts in bringing together a diverse range of essays concerning research law in a single publication. They have successfully scoped the most important interconnecting themes relating to research law and have produced a publication that will undoubtedly be of great assistance to a wide audience, including, researchers, lawyers, public officials, teachers and students. Although its principal orientation is towards people involved directly in research, the well-crafted and 'user-friendly' summaries of such matters as privacy and access to information, environmental law, consent and information disclosure, employment law and intellectual property will almost certainly be of interest to a much broader audience.

This excellent and original publication deserves the widest possible dissemination amongst people involved in the research community. The issues it addresses are of the utmost importance. Researchers owe it to themselves and to the various constituencies they serve to have a clear understanding of their legal rights, obligations and potential liabilities. Such knowledge will be instrumental in maximizing the effectiveness of their professional activities. This book provides a most useful first step towards achieving relevant knowledge in this complex and problematic area.