



<http://researchspace.auckland.ac.nz>

ResearchSpace@Auckland

Copyright Statement

The digital copy of this thesis is protected by the Copyright Act 1994 (New Zealand).

This thesis may be consulted by you, provided you comply with the provisions of the Act and the following conditions of use:

- Any use you make of these documents or images must be for research or private study purposes only, and you may not make them available to any other person.
- Authors control the copyright of their thesis. You will recognise the author's right to be identified as the author of this thesis, and due acknowledgement will be made to the author where appropriate.
- You will obtain the author's permission before publishing any material from their thesis.

To request permissions please use the Feedback form on our webpage.

<http://researchspace.auckland.ac.nz/feedback>

General copyright and disclaimer

In addition to the above conditions, authors give their consent for the digital copy of their work to be used subject to the conditions specified on the Library Thesis Consent Form.

The Organisation and Management of Clinical Research in Academic Medical Centres

Chapters I-VII
Bibliography
Appendices A-E

Candace Gale Pettus

A thesis submitted in partial fulfilment of the requirements
for the degree of Doctor of Philosophy
The University of Auckland
2003

PHILSON LIBRARY
Faculty of Medical & Health Sciences
Park Road, Grafton
AUCKLAND

Abstract

Clinical research is a traditional function of academic medicine and is vital to the development of new therapies and therapeutics. Most clinical research takes place within academic medical centres (AMCs), which are complex organisations operating at the juncture between clinical care, teaching and research. However, the environment in which academic medical centres operate has experienced significant turbulence over the last 10 years. Concerns have been raised about how clinical research is being managed in this dynamic environment. The question arises: What elements of organisational structure are important in the management of clinical research in academic medical centres?

Working within the framework of organisational theory, this study employed a multi-method investigative process to explore the context of clinical research management in AMCs in five countries: the United States, the UK, Canada, Australia and New Zealand. Archival data, a survey questionnaire and key informant interviews were analysed to develop a description of the context and structure of modern clinical research management. The results describe four structural models for clinical research management: (1) the established university-based model; (2) the hospital-based model; (3) the research institute model; and (4) the UK-NHS trust hospital model. In addition to formal organisational structures, this study has found that the use of informal structures, such as liaison devices and other integrative mechanisms are important to facilitate communications, co-ordinate complex activities and mitigate tensions between professionals and managers, and between the hospitals and universities that comprise academic medical centres.

The findings from this study contribute to the body of knowledge on complex organisations in general and AMCs in particular. Moreover, it is anticipated that the findings from this study might be useful in the planning and development of clinical research management practices in academic medical centres as well as other professional research organisations.

Keywords: academic medical centre, clinical research, organisational structure, liaison roles

Acknowledgements

Many people have been instrumental in this journey. My supervisor, Associate Professor Marie Wilson, has provided unending patience, guidance and expertise. For this I am very grateful. I would also like to thank my colleagues at Auckland Healthcare Services Limited for their support and understanding, especially on those mornings after the late nights. Most importantly, I am indebted to the respondents and interview participants who freely gave their time and were open in sharing their views and attitudes.

I wish to also acknowledge Mr Jim Greenslade and Mr Richard Warburton of the School of Engineering at the University of Auckland for their assistance in overcoming programming and technical hurdles in the development of the Internet survey data capture methodology. Liz Hardwick-Smith patiently constructed the internet web pages required for the survey. Professor David Thomas kindly advised on the construction of this dissertation.

Above all, my thanks go to my family, Daryl, Jazmin and Solana, for their unwavering support, encouragement and love. This thesis is dedicated to my father, Bill, the smartest man I know.

Table of Contents

Abstract	ii
Acknowledgements	iii
List of Figures	v
List of Tables	vi
List of Abbreviations	vii
Chapters	
I Challenges for clinical research management	1
II Last tango in Toronto: Clinical research in action	19
III A theoretical framework for investigating academic medical centres	28
IV Approaches for researching organisations	56
V The contemporary context of academic medical centres: Phase one of the research	70
VI Inside the academic medical centre: Second and third phases of the research	100
VII Conclusions and implications	154
Bibliography	
Appendices	
A Glossary of terms	
B Survey instrument and interview guide	
C Survey data	
D Perceived organisational structures	
E Importance and effectiveness of tasks	

List of Figures

Figure 1.1	Overall Research Design	14
Figure 3.1	Control and Authority in the Professional Bureaucracy	43
Figure 3.2	Characteristics of Organisations along the Structural Continuum	53
Figure 4.1	Data Profile: sources of breadth and depth	68
Figure 6.1	Study Design for Phases Two and Three	106
Figure 6.2	University Hospital Structure (USA 47)	124
Figure 6.3	University (GCRC) and Hospital Structure	125
Figure 6.4	Research Institute (USA 45)	127
Figure 6.5	NHS Trust Hospital (UK 59)	131
Figure 6.6	Importance and Effectiveness of Processing Applications for Research Approval (US)	139

List of Tables

Table 4.1	Data Gathering Matrix	62
Table 4.2	Data Reliance Matrix	64
Table 6.1	Clinical Research Management Tasks	103
Table 6.2	Sample Population Characteristics	108
Table 6.3	Survey Response Rates	110
Table 6.4	Responses by Country	111
Table 6.5	Response Gaps between Task Effectiveness and Importance: a comparison of 'achievers' and 'non-achievers' (all countries)	140

List of Abbreviations

- AAMC** American Association of Medical Colleges
- UCLA** University of California, Los Angeles
- AIDS** Acquired immunodeficiency syndrome
- AMC (or AHC)** Academic medical centre (or Academic health centre)
- AUS** Australia
- BA** Bachelor of Arts
- BCRI** British Columbia Research Institute
- BSc** Bachelor of Science
- CEO** Chief Executive Officer
- CHE** Crown Health Enterprise (New Zealand)
- CRC** Clinical Research Centre (United Kingdom)
Co-operative Research Centre (Australia)
- CRN** Clinical Research Network (United Kingdom)
- CSC** Clinical Science Centre (United Kingdom)
- CTC** Clinical Trials Centre (at NHMRC, Australia)
- CTO** Clinical Trials Office
- FDA** Food & Drug Administration (United States)
- GCRC** General Clinical Research Center (United States)
- GCRP** Good Clinical Research Practice
- HPB** Health Protection Board (Canada)
- HRC** Health Research Council of New Zealand
- HSC** Hospital for Sick Children (Toronto)
- ICH-GCP** International Committee for Harmonisation – Good Clinical Practice
- IND** Investigational New Drug (FDA classification)

IP Intellectual property OR Internet protocol

IRB Institutional Review Board

LHRI Loeb Health Research Institute

MA Master of Arts

MBA Master of Business Administration

MD Doctor of Medicine

MRC Medical Research Council (UK)

MS Multiple sclerosis

MSc Master of Science

MUHC McGill University Health Centre (Canada)

MUSC Medical University of South Carolina

NASA National Aeronautics and Space Administration

NHMRC National Health and Medical Research Council (Australia)

NHS National Health Service (United Kingdom)

NIH National Institutes of Health (United States)

NZ New Zealand

PhD Doctor of Philosophy

R&D Research and development

RDSU R&D Support Unit

REB Research Ethics Board (Canada)

RHA Regional Health Authority (United Kingdom)

RN Registered Nurse

UCLA University of California, Los Angeles

UCSF University of California, San Francisco

UHC University Health System Consortium

UK United Kingdom

UMHC University of Minnesota Health Center

URL Universal resource locator

US/USA United States

WWW World Wide Web