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The Organisation and Management of Clinical Research in Academic Medical Centres

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A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy
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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
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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