REGULATING THE REGULATORS

AN EMPIRICAL STUDY OF THE INFLUENCES ON THE RESEARCH GOVERNANCE PRACTICES IN VICTORIAN PUBLIC HEALTHCARE AGENCIES

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DECLARATION

Doctor of Philosophy Declaration "I, Bernice Davies, declare that the PhD thesis entitled *Regulating the regulators. An empirical study of the influences on the research governance practices in Victorian public healthcare agencies* is no more than 100,000 words in length including quotes and exclusive of tables, figures, appendices, bibliography, references and footnotes. This thesis contains no material that has been submitted previously, in whole or in part, for the award of any other academic degree or diploma. Except where otherwise indicated, this thesis is my own work".

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ABSTRACT

This thesis investigated how the National Mutual Acceptance (NMA) model of single ethical review has currently impacted, and how it is likely to impact the future, on the research governance practices of public healthcare agencies participating in multi-site clinical trials.

This study sought to describe the variables associated with the impact of the NMA through the theory of Institutional Isomorphism proposed by DiMaggio and Powell , which proposes that comparable organisations develop similarities in order to appear legitimate to their stakeholders. Consolidation is influenced by: coercive isomorphism, which involves pressures from other entities on which they are dependent; mimetic isomorphism, which refers to the tendency of an organisation to imitate a more successful organisation; and normative isomorphism, which is driven by professional pressures. Data was collected in two phases.

Phase One focused on the collection of quantitative data relating to perceptions of the importance of research and the impact of the NMA. Phase Two involved collection of qualitative data to explore the reasons behind current irregularities in the NMA and expectations of the future.

Although participants agreed that the NMA could provide isomorphic pressures, there were concerns regarding bureaucratic inconsistency that created uncertainty in the processes. The strongest isomorphic influence provided by the NMA was coercive pressure, which was also identified as a possible future mechanism. In contrast to findings in other literature, neither mimetic nor normative pressures were perceived as influential because emphasis on the practices of individual agencies prevented a coherent system from developing.

The study made three contributions to Institutional Isomorphism theory. It identified the importance of robust coercive forces to allowing mimetic and normative forces to emerge. It also highlighted the need for agencies to recognise implications of research governance beyond their own organisational boundaries and the need to quantify the responsibilities of governance personnel to strengthen coercive impact.

Recommendation included the need to address: organisational leadership of the NMA, to strengthen the knowledge base through education and training, the development of a stakeholder engagement framework and opportunities to expand the NMA.

This research provides new insight into understanding research governance in the context of the Australian public healthcare sector and provides a model though which further exploration may be undertaken.

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LIST OF KEY TERMS AND ACRONYMS

Accepting site	A healthcare agency that accepts the review of a NMA proposal reviewed by a NHMRC certified HREC
AU RED	Australian Research Ethics Database
CAS	Central Allocation System (Victoria)
COAG	Council of Australian Governments
Code, the	The Australian Code for the Responsible Conduct of Research
CPI	Coordinating Principal Investigator who manages the lead site team of a multi-site research application
CRO .	Contract research organisation
CTRA	Clinical trial research agreement.
GCP	Good Clinical Practice
Healthcare agency	Publicly funded healthcare provider that delivers care through associated organisations
HREC	Human Research Ethics Committee
Indemnity	In respect to clinical trials, the indemnity a legally binding promise provided by the commercial research sponsor to accept the risk of loss or damage the healthcare agency may suffer and/or to compensate the agency for the loss or damage.
ISO	International Organization for Standardization
Lead site	The research team that applies for the ethics review on behalf of all the agencies intending to participate in the research project
Medicines Australia	Organisation that represents the Australian innovative medicines industry
National Statement	The National Statement on Ethical Conduct in Human Research published by the NHMRC.
NEAF	National Ethics Application Form
NHMRC	The National Health and Medical Research Council.
NMA	National Mutual Acceptance.
PI	Principal Investigator
RGO	Research Governance Officer
Sponsor	Research sponsor takes ultimate responsibility for the research and/or financing for that research.
SSA	Site Specific Assessment
TGA .	Therapeutic Goods Administration
VARN	Victorian Association of Research Nurses
VMIA	Victorian Managed Insurance Authority
VRGN	Victorian Research Governance Network
VSM	Victorian Specific Module

CHAPTER ONE: INTRODUCTION

1.1 Background

The importance of responsible conduct in all areas of research involving human participants is indisputable. Publications of medical research, however, describe research in terms of outcome, the importance of what was found and who was impacted by the findings and, more recently, the economic benefits of the discovery. Issues of oversight or scrutiny are typically described in disparaging terms, such as a burden, cost or a delay, with the implication being that it is separated from the researcher in their pursuit of knowledge.

This position is problematic on a number of levels. It negates the contribution of the processes involved in research review and devalues the actions of the regulatory personnel involved and the culture they ascribe to. Thus, while the logistics of managing "overly-bureaucratic and duplicative review processes" (Manville, Hackett, Gunashekar, & Morgan Jones, 2013,p. xiii) have been extensively debated world-wide, the nature and mores of the regulatory community has not.

Globally, changes in the biomedical research landscape have placed greater emphasis on how research and development is performed and measured (Battelle Technology Partnership Practice, 2015). Multi-site, commercial clinical trials offer financial and clinical advantages which has induced many countries, including Australia, to create an accommodating research environment. In Australia, it is estimated that around 1000 new clinical trials are commenced annually by pharmaceutical, biotechnology and medical device companies representing a $1 billion investment (Australian Government & The Australian Trade and Investment Commission, 2017). It has been estimated that more than 18,000 Australians annually participate in clinical trials sponsored by the medicines industry (Medicines Australia, 2011). Many trials involve international sponsors. The majority of the trials are undertaken at multiple research sites internationally in order to expedite data collection. In order to remain a competitive host in the global market, the Australian Government, in partnership with industry and other

stakeholders, is implementing a series of reforms to encourage further and ongoing investment (National Health and Medical Research Council, 2014d).

Many challenges relate to growth of the pharmaceutical industry, a leading world-wide investor and stakeholder in commercial development, and their need to address the rising expectations of investors for a reasonable return of investment (Battelle Technology Partnership Practice, 2015). For commercial clinical trials, timeliness of the trial "start-up" or commencement is a critical factor in maximising the period of commercial returns. The lack of timelines of research approval has been identified as a significant disincentive to investment (Campion & Engwall, 2013; NSW Ministry of Health, 2013). The clinical trial industry has been a major influence on regulatory reform of the bureaucratic processes around research review.

Australian government initiatives to create an optimal environment for commercial investment in multi-site clinical trials has propelled the behaviour of the research regulatory community sharply into focus. Efforts towards greater efficiency are directed at the sector as a whole. The National Mutual Acceptance (NMA) of single ethical review, for example, is based on the principle of cooperation between entities.

Under the NMA, a proposal to conduct a human research project at public healthcare sites in more than one participating jurisdiction may submit to a single reviewing human research ethics committee (HREC) that has been certified by the National Health and Medical Research Council (NHMRC). Organisations from participating jurisdictions then accept the single scientific and ethical review in place of conducting their own review. Each organisation undertakes an individual site specific or governance review to determine the capacity of the organisation to undertake the research. Together the ethical approval and site specific authorisation provide the permission for the study to be conducted.

The NMA commenced in 2013, following several years of state based and inter-state mutual acceptance. It is operationalised through the governments of participating jurisdictions, who provide comprehensive guidance in how to engage with the system. Despite this guidance, concerns remained of excessive administration requirements and a lack of clarity, consistency, transparency and timeliness in the review processes

(Health Outcomes International, 2015). This raised questions about why those involved in the NMA continued to behave in ways that that fuelled these concerns.

This study examined governance literature to determine the influences on organisational decision-making behaviours in relation to multi-site research undertaken in the Australian public healthcare sector. Previous theories of how corporate governance functions have identified competing pressures for convergence and organisational differentiation (Hung, 1998). These theories have relevance to the public sector, but the challenge of organisational research governance in the context of a national system is to understand the nature of variations in conformity. According to the theory of Institutional Isomorphism, organisational survival depends not only of their activities but also on the organisation being perceived as acceptable and credible, or in other words, legitimate (DiMaggio & Powell, 1983). There is a tendency for organisations to develop similarities when faced with the same environment. The multi-faceted nature of public health suggests that different measures of legitimacy may apply.

A review of current literature indicated a lack of both theoretical and empirical research on the nature of research governance within a national model of single ethical review in Australia. This was an important gap, not only to define research governance in this setting, but also to examine its influences.

In order to provide a basis for the current investigation, the structure of this chapter is organised as follows. Section 1.2 provides the study aim; Section 1.3 presents the conceptual framework developed to conduct the study; Section 1.4 outlines the context of the study; Section 1.5 discusses the methodology of the study, Section 1.7 explains the contribution to knowledge; Section 1.8 states the significance of the study; and Section 1.9 describes the structure of the thesis. The summary of Chapter One is provided in Section 1.10.

1.2 Aim of the study

Organisational governance of research within a national system is an emerging field but the NMA influence on the performance of healthcare agencies has not been empirically investigated. This study employed the theoretical lens of Institutional Isomorphism to

determine the how coercive, mimetic and normative isomorphism contributed to the NMA impact.

The major performance measure or benchmark of the NMA is that the scientific and ethical review is completed within 60 days. Although there is no formal benchmark for authorisation from the participating organisations, there is an assumption that organisational endorsement is provided within the same timeframe. Implicit in this assumption is that there are comparable research governance processes and that the NMA will have a similar impact at each participating site. The expectation of homogeneity between organisations faced with the same constraints is in keeping with Institutional Isomorphism theory. Research literature, however, indicates that participating organisations are heterogeneous in practice. Therefore, in order to understand the effect of the NMA, this research was directed at the intersection between the Australian government initiative to streamline multi-site research review and the healthcare agencies performing the research. The study sought to identify and examine factors influencing the behaviour of regulatory personnel in these organisations. It was not intended to review or analyse the components or nature of commercial clinical trials other than their impact on the regulatory personnel.

The aim of this study was to explore how the NMA has impacted on the research governance practices of public healthcare agencies participating in multi-site clinical trials and to make recommendations for future regulation.

The main question addressed by this study was:

> What are the coercive, mimetic and normative pressures that influence public healthcare agencies in Victoria to comply with the National Mutual Acceptance?

The study identified and described variables associated with the current and future impact of the NMA. Propositions and associated hypotheses are presented in Chapter Four.

1.3 Conceptual framework

The conceptual framework of the study was designed to provide a theoretical underpinning of the evaluation of research governance effectiveness. The conceptual model involved a cross-over of the major theoretical constructs paired with practical outcomes of research governance which then identified key drivers or mechanisms of adoption of the NMA.

Measures of the practical outcomes of research governance were based on the four pillars model for analysing the global attractiveness of the clinical trial environment in Australia, presented at 2006 forum on clinical trials by a combined committee of government and industry representation. The four pillars for analysis were: timeliness, quality, value and capacity (Department of Industry, 2006). In this model, the four pillars measure performance of organisational governance strategy.

The major theoretical components of Institutional Isomorphism involved in this model were the isomorphic pressures of coercive, mimetic and normative influences and organisational legitimacy (DiMaggio & Powell, 1983). The theory proposes that, for organisations to survive, they must appear successful or legitimate to their stakeholders. Isomorphism refers the tendency of organisations, under similar constraints, to develop similar processes or structure in order to appear legitimate. Literature suggests that perception of legitimacy may vary depending on the audience (Deephouse, 1996).

The resulting constructs used in the model reflect that different perceptions of legitimacy are driven by different isomorphic pressures. Coercive isomorphism was driven by government pressure to achieve timeliness of review. Mimetic isomorphism was driven by stakeholder pressure of perception of organisational value and capacity. Normative isomorphism was driven by professional pressure to achieve perceptions of quality. The conceptual model was further developed in Chapter Four.

1.4 Context of the study

This study focused on how a government initiative, the NMA, impacted on the research governance practices of Victorian public healthcare agencies undertaking multi-site clinical trials. The scope was restricted to a single jurisdiction and study type to limit

the effect of different legislative and regulatory requirements. Within these constraints, a tension between the goals of the national system and the standard focus of healthcare agencies was identified and forms the context in which this study is set.

World-wide growth of biomedical sciences has resulted in the escalation of multi-site clinical trials involving different countries, which has, in turn, led reconsideration and reform of existing regulatory frameworks around research review processes. Many of these reforms were intended to address concerns about repetitious and overly bureaucratic processes that delayed the approval of clinical trials (Clinical Trials Action Group, 2011).

Initiation of clinical trials reform in Australia stems largely from government. The aim of the Federal Departments of Industry and Science and of Health are to rationalise research bureaucracy through standardisation and to harmonise research processes through streamlining administrative processes. State and Territory governments operationalise reform in the public sector through existing relationships with public healthcare agencies. These designs are intended to increase Australia's international advantage in clinical research and to reap the clinical and financial advantages of clinical trial participation. In keeping with the international developments, Australia has also implemented a national approach to single ethical review of clinical trials with the publicly funded health sectors of each State and Territory. The dominant attribute of the NMA is to provide a system, where all participating entities behaved according to set guidelines, and success was measured through the effectiveness of the system overall.

In contrast, Victorian health policy is set by the Victorian Government and supported by the Department of Health and Human Service (DHHS) as well as the departments of Premier and Cabinet (DPC) and Treasury and Finance (DTF). Victoria's public health agencies are incorporated public statutory authorities, and thus independent legal entities (Victorian Department of Health, 2013c) embodied with the philosophy of self-governance. They are governed by Boards of Directors (Boards), the members of which are appointed by the Governor-in-Council on the recommendation of the Minister for Health. Boards are obliged to act within defined legal and financial requirements through a devolved governance process that enables them to make local decisions to

meet local needs. The standard organisational structure and division of power of a public healthcare agency is hierarchical (Figure 1.1).

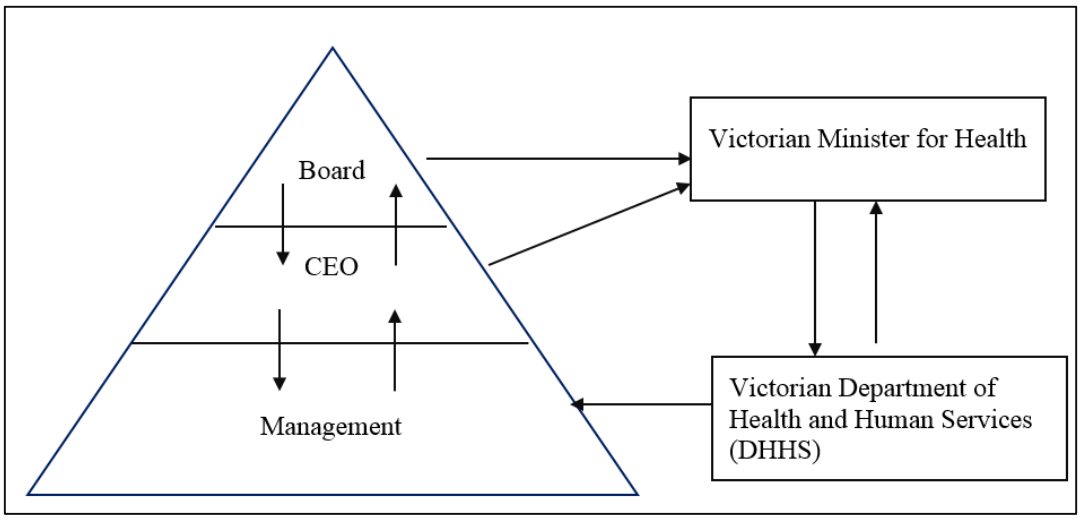

Figure 1.1: Organisational structural apex

Adapted from *Corporate Governance in the Victorian Public Health Sector* (Doctoral dissertation) by M. Fitzpatrick, 2008, p8.

In the hierarchical model, the Board of Directors is placed at the top of the apex and the Chief Executive Officer (CEO) on the next level. This governance structure allows decisions and reporting of management to be passed up and strategic decision-making passed down from the Board. Both the Board and the CEO have obligations to the Minister for Health, who has ultimate power, and the Department of Health and Human Services DHHS (Fitzpatrick, 2008).

The hierarchical structure provides an effective governance mechanism for reporting on defined performance targets. Health strategy centres largely on financial stewardship and clinical care performance and ensuring compliance with statutory requirements (Victorian Department of Health, 2008). However, it may be difficult to determine performance targets when the goal is not clearly defined. Currently agencies are not accountable to the Minister for Health for the performance of research they perform.

There is also ambiguity in the definition and scope of research governance. It has been defined in a variety of ways, from the tasks through which organisations ensured the integrity of their research (National Health and Medical Research Council & the

Australian Research Council and Universities Australia, 2007) to a system through which research is managed and which involves all participating entities (Shaw, Boynton, & Greenhaigh, 2005). In the NMA model of single ethical review, the term is applied to distinguish those activities which determine a healthcare agency's capacity to perform a research project from the ethical review (Department of Health and Human Services, 2016).

Single ethical review in Australia presents a complex and conflicting picture. The timeliness of clinical trial approvals has been identified as a key factor in the development of a strong and unified medical research culture (Clinical Trials Action Group, 2011; Health Outcomes International, 2015; Khan, Maccarrone, Jones, Monk , & Nielsen 2013) but the existence of multiple governance practices, as indicated in the comparison of submission practices, presented in Appendix N, suggests persistent focus on indiviual organisational practices.

This literature review identified gaps in literature about how the Australian NMA was impacting on the research governance practices of participating healthcare agencies, and suggested a there was a need to explore the roles and responsibilities of research governance personnel. It raised questions about why organisations were responding to the single ethical review system in ways that continued to lead to duplication and protracted review.

1.5 Methodology of the study

The research employed a mixed methodology approach. Mixed methods research combines quantitative and qualitative research methods in the same research inquiry. Such approaches can help develop rich insights into areas that cannot be fully understood using only a quantitative or a qualitative method (Venkatesh, Brown, & Bala, 2013).

Primary data were collected in in two phases. The first phase involved the collection of quantitative data regarding the coercive, mimetic and normative impact of the NMA in Victoria through an anonymous, electronic survey of 149 respondents. The second phase focused on qualitative data exploring the experiences 21 research leaders

involved in the NMA. Leaders in the context of this research were defined as those who were actively involved in developing awareness of single ethical review, either through their employment or as part of a professional association. Comments from Phase One were included in the thematic analysis of Phase Two to corroborate the leaders' observations.

Quantitative data were analysed to determine the significance of the results. Cross-tabulations were performed for each question along with Pearson's Chi-square (x^2) testing for independence of the items within each section. Factor analysis was performed to identify the correlation among the variables in all four constructs of the study. Thematic analysis of the qualitative data collected in the second phase was undertaken with a focus on how the NMA was likely to impact on research governance of multi-site research in the future. In accordance with guidance provided by Venkatesh et al. (2013), triangulation was applied to the qualitative and quantitative findings to corroborate and integrate them in a shared domain of empirical research.

1.6 Existing literature

Concerns regarding variation in research governance practices impeding multi-site research have been increasingly represented in literature (Braverman & Sidhu, 2011; Gorman, 2011; Health Outcomes International, 2015; Manville et al., 2013; Prosser, Davey, & Gibson, 2015; Webster & Temple-Smith, 2013; White et al., 2016) but there was a lack of empirical evidence that defined research governance, especially in relation to how research governance was practiced in relation to a national model of single ethical review.

A literature search was undertaken to examine how corporate governance was defined. Scholars have approached analysis of corporate governance through a variety of theoretical perspectives in order to identify the values, norms and principles that underpin governance systems and approaches (Cornforth & Edwards, 1999; Hough, McGregor-Lowndes, & Ryan, 2005; Hung, 1998). This suggests that research governance, a sub-section of corporate governance, could also be viewed as contextual.

Guidance on research governance from Australian regulatory bodies emphasise the organisational responsibilities for research integrity (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007). In contrast, the guidance for participating in the NMA emphasised the connections between the activities of different parties (Department of Health and Human Services, 2016). Studies of the introduction of national systems suggest the likelihood of tension between local needs and national goals (Franck, Pendleton, Pittam, Preece, & Aynsley-Green, 2004) and that not all organisational attributes are amenable to pressures to adapt to national approach (Ashworth, Boyne, & Delbridge, 2007). Management needs to the benefits of centralisation against their own perceptions of reduced autonomy and control (Howarth, Kneafsey, & Haigh, 2008).

These findings inferred that a multidimensional perspective was required to promote organisational change. The research employed Institutional Isomorphism (DiMaggio & Powell, 1983) to explore this phenomenon.

1.7 Contribution to knowledge

Although there is an extensive literature on public sector corporate governance, public sector research governance is an emerging field of knowledge. This study makes an original contribution to the literature because it is the first comprehensive investigation into research governance practices of public healthcare agencies involved with the National Mutual Acceptance (NMA).

Extant literature has largely defined research governance through its negative effect on research projects. Although these studies delineated the tasks that gave rise to their concerns, viewing the problems in isolation from the research governance culture has created difficulties in exploring why the behaviours that give rise to these tasks have occurred.

The study used Institutional Isomorphic theory to explore the degree to which pressures from coercive, mimetic and normative isomorphism fostered adoption of similarities between healthcare agencies. Presenting research governance as a social construct allowed examination of the impetus behind the tasks rather than just the tasks

themselves. Thus the study also makes a significant contribution to knowledge related to the reasoning of research governance personnel, and how those decisions are viewed in relation to intervening variables of age, education, gender, role, level and years of experience.

The study has made meaningful contribution to the body of knowledge around Institutional Isomorphism by identifying the importance of coercive pressure to the development of mimetic and normative pressures. In contrast to previous findings of mimetic pressures developing though uncertainty, this study found that lack of coercive strength led decision-makers to copy away from the intended direction. It also found that weak coercive pressures allowed organisations to retain their own local culture, rather than pursue a cross-organisational standards.

The conceptual framework developed in this thesis provides a model for others to use to identify and analyse the critical elements of research governance performance in relation to the NMA. Identification of separate legitimacy drivers, related to coercive, mimetic and normative isomorphism provides a potential basis for future exploration of this area.

1.8 Significance of the Study

The study makes a practical contribution to current policy debates around continued delays in research approval by the identification of research governance personnel as stakeholders in the adoption of a national model.

The study identified that variations of research governance practices were a result of the values and practices of their parent healthcare agencies. Thus, to be fully effective, the NMA needed to involve changes to the social construct around the NMA. According to Scott (Scott, 2004) organisational behaviours are entrenched in the rules, norms, and practices which have become established as authoritative guidelines. The impetus behind this authority may vary. In complex organisations, such as healthcare agencies, local cultures are established and reinforced through multiple activity pathways. For example, standard clinical care is regarded differently in separate organisations, which can have different impacts on the budget required to perform the research. This implies

that the development of appropriate regulatory and governance policies around the NMA required formal contribution from healthcare agency personnel.

The study built on literature which has previously identified "invisibility" of research administrators as problematic. Dunscombe (2008) noted that visibility of these roles would be a "starting point to combating some of the problems associated with unclear roles and responsibilities, including unwitting boundary crossing and inappropriate concentration and use of power" (p. 81). Kasule, Wassenaar, IJsselmuiden & Mokgatla (2016) found that the administrators' potential to improve research ethics review performance was diminished because of variance in their expertise and responsibilities. They further recommended capacity-building initiatives for administrators, such as standardisation of job titles, remuneration scales and vocational pathways. The current study supported previous findings, and found that lack of harmonisation between sites obstructed the realisation of the NMA.

In contrast to literature that has identified customary divergence between research applicants and regulators (Allen, 2008), the findings from the current study suggest that groups are comparable. It was found, however, that middle and senior management were more likely to indicate uncertainty and lack of support for activities that support the NMA. This suggests that for the system to succeed, stronger leadership of single ethical review within the healthcare agencies is required.

1.9 Structure of the Thesis

This thesis consists of nine chapters. *Chapter Two* reviews the literature on dominant theories of corporate governance, with particular reference to different concepts involved in organisational legitimacy and the theory of Institutional Isomorphism applied in review of the public sector.

Chapter Three addresses the context of the study, the intersection of Victorian public health care agencies and a federal government initiative. This chapter also examines the terminology used to define this intersection as critical factors in research governance of healthcare projects.

Chapter Four presents the conceptual framework, developed for the study, to analyse the effectiveness of research governance.
In *Chapter Five*, the research design and methodology used to undertake this research are presented. A mixed methods design was used as both quantitative and qualitative research methods were integral to the study conclusions.

Chapter Six present the results of the electronic survey that formed the basis of Phase One investigations, the analyses of the data and the statistical methods applied to the data in the study. Information about the characteristics of the sample used as part of the analysis is also described in this chapter.

Chapter Seven presents results of the interviews that formed the basis of Phase Two investigations and the qualitative analyses of the data in the study. Phase Two was built on the findings and suggestions from Phase One.

Chapter eight provides the interpretation of the results. This chapter also presents findings as they relate to the conceptual framework including findings in response to the research questions and research hypothesis. Data integrity and triangulation of the quantitative and qualitative data is also presented.

The conclusions, discussion and recommendations are reported in *Chapter Nine* along with an acknowledgement of the limitations of the study and recommendations for future research.

1.10 Summary

The intent of this introductory chapter was to present the background to the study and set the foundation of the thesis. It also provided a synopsis of each chapter of the thesis.

Chapter Two provides a review of the relevant literature regarding corporate governance, research governance and a critical analysis of current theories of corporate governance before applying governance theory to the examination of research governance.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

A literature search was conducted using Web of Science, the Cochrane Library, JAMA and MEDLINE available on Victoria University Library's website. Searches of the academic literature were conducted between January 2014 and June 2017. Corporate governance literature was searched through the keywords "corporate governance", delimited by "theory' or "institutional isomorphism". Research governance was searched through the key word search term "research governance", delimited by "single ethical review", "streamlined ethical review" and "public health".

After an extensive literature search that found localised literature tended to be industry based, a decision was made to perform a bibliographical search of previously published reference lists. Research governance is a contemporary phenomenon and, as yet, has limited foundation.

The Chapter is presented as follows. Section 2.2 looks at the complexity of corporate governance, noting that literature presents it as a highly contextual concept that varies significantly depending on the environment in which the organisation is positioned. Section 2.3 explains the development of research governance, how the business aspects of research have driven bureaucratic reform. The section involves a discussion of challenges that arise in the implementation of national framework. Section 2.4 presents the theoretical basis to the study of governance. This leads to Section 2.5 describing Institutional Isomorphism theory, Section 2.6 expanding on the concept of legitimacy concludes the literature review and Section 2.7outlining the theory of Institutional Isomorphism. A summary of the weakness in Institutional Isomorphism approach is outlined in Section 2.8. Section 2.9 addresses why this theory was used in this study. Section 2.10 summarises this chapter.

2.2 Corporate governance

This section explores the concept of corporate governance within the public sector and how it encompasses the rules, relationships, policies, systems and processes through

which authority within organisations is exercised and maintained. While public sector governance has been informed and influenced by the principles and actions of private sector, public sector agencies operate in an era of increased political, socio-economic and environmental interconnectedness. Decision-making processes of government departments and agencies increasingly relate to other government bodies and to organisations outside the government sector.

2.2.1 Concepts of corporate governance

The complexity of corporate governance is difficult to capture in a single definition. In actuality, corporate governance is a highly contextual concept; processes and practices vary significantly depending on the environment in which they are applied (Armstrong & Sweeney, 2002; Crow, Lockhart, & Lewis, 2013; Edwards & Clough, 2005; Hough et al., 2005). Governance definitions are many and varied, presenting scholars with descriptive and conceptual challenges. A review of the literature has determined three perspectives through which governance may be viewed: as structure and processes; as human activity; and as a decision-making mechanism.

At its narrowest, corporate governance is about how an organisation is "directed and controlled" (Cadbury, 2002, p 1). It is about the structures and processes in place to facilitate organisational practises that ensure accountability and the improvement of performance (Barrett, 2002). These include mechanisms to monitor effective management and systems to ensure legal compliance and prevent improper or unlawful behaviour (Edwards & Clough, 2005). Governance from this perspective emphasises the composition of institutionalised rules and systems, including: the formal delegation of power to the Board of Directors; lines of delegation and reporting; and strategic direction.

Governance can also be viewed in terms of human activity that is concerned with creating conditions for ordered rule and collective action (Stoke, 1998) and which increasingly places attention on a broader set of relationships (Barbazza & Tello, 2014; Clarke & Dela Rama, 2008; Dwyer & Eagar, 2008). Broader sets of relationships may include those involved with, or with an interest in, the organisation, such as employees, directors, suppliers, shareholders and stakeholders or may even include those served or

affected by the organisation, such as customers and local communities (Edwards & Clough, 2005). The multiplicity of organisational interactions and needs highlights how culture, policies or strategies impact on "the ways in which it deals with its various stakeholders" (Barrett, 2002 , p 2). An example of the concept of human interactions as central to corporate governance is illustrated in the 2004 *OECD Principles of Corporate Governance*, which states that corporate governance involves a "set of relationships between a company's management, its board, its shareholders and other stakeholders" (Organisation For Economic Co-Operation And Development, 2004, p.11). Defining governance as an activity involving human values or morals infers that it is not static and that significant changes may be wrought through stakeholders and the socio-political environment.

The third perspective of governance, as a decision-making mechanism, is concerned with effective policy outcome. The impact of strategic decision-making on performance, is an important consideration for governance scholars, although assumptions of congruence in the "black box" or the internal dynamics of the board of governance processes cannot be assumed (Crow et al., 2013).

Corporate governance theory involves conceptual, cultural, contextual and disciplinary facets that raise questions regarding how values, norms and principles underpin governance systems and governing approaches.

2.2.2 Corporate governance reforms

Sound corporate governance practices also contribute to meeting the challenges of global competition. Following a number of high profile corporate collapses, such as HIH insurance and One Tel in Australia, and Enron and WorldCom in the USA, many countries revised their regulatory approaches to improve corporate governance (Rebecca & Gørgens, 2009). Australia has also undertaken significant corporate governance reforms including the *Corporate Law Economic Reform Program (Audit Reform and Corporate Disclosure) Act 2004 (*Cth.) (AustlII.) and the Australian Securities Exchange (ASX) *Corporate Governance Council's Principles of Good Corporate Governance and Best Practice Recommendations* (ASX Corporate Governance Council, 2007, 2014).

The Australian public sector has focussed on the need to improve service efficiency and effectiveness, especially in relation to commercialisation, corporatisation and privatisation of government organisations (Commonwealth of Australia, 2014). Major legislation notably the *Public Service Reform Act* 1984 (Cth.) (AustlII.) and the *Public Service Act* 1999 (Cth.) (AustlII.), in addition to the findings of a number of inquiries and task forces, attest to the concern from a series of governments that restructure of the public sector was required. In 2010, for example, the Rudd Government released "*Ahead of the Game: Blueprint for the Reform of Australian Government Administration"* which outlined a comprehensive reform agenda in four broad areas: meeting citizens' needs; providing leadership and strategic direction; developing Australian capabilities, and operating efficiently and at a consistently high standard (Australian Government, 2010). This blueprint has led to focus on greater integration of services including the development of long term strategic and leadership capability of the Australian Public Service, accompanied by new accountability measures such as the introduction of cross-portfolio outcomes and agency capability reviews (Australian Public Service Commission, 2014).

The concept of governance therefore is considered fundamental to organisational success (Carrington, DeBuse, & Lee, 2008) and a mechanism for increasing a company's long term viability by enhancing the business's value and paving the way for growth (Australian Institute of Company Directors, 2014).

2.2.3 Elements of governance

Standard corporate governance elements such as accountability, performance and conformance are not static but affected by the "prism of constitutionalism, managerialism, or any other organising theory of public administration that holds sway from time to time" (Edwards, Halligan, Horrigan, & Nicoll, 2012, p. 18).

Accountability is the cornerstone of effective governance of both the government and non-government organisations. In broad terms, accountability develops when the performance of tasks or functions by one entity are subject to another's oversight, direction or request that they provide information or justification for their actions.

Accountability provides a framework through which oversight is provided. In the public sector, such oversight ensures that: government strategy is being met; there is value for money in the provision of public services; and confidence in the government and expected responsiveness to the community is being undertaken (Stapenhurst & O'Brien). Contemporary governance may involve the different conceptions of hard and soft attributes and of horizontal and vertical planes.

2.2.3.1 Hard and soft governance. Governance strategies of well-governed organisations include not only formal and structural aspects (or hard governance factors) but also behavioural and relational aspects (or soft governance factors). Hard governance variables are measureable, such as the proportion of outside directors on the Board or performance that can be compared to a target. Soft governance entails the dynamics of behaviour, such as the nature of the relationship between the Chair of the board and the Chief Executive Officer (CEO), how the Board behaves when making a decision and organisational culture. Literature suggests it is the interplay of hard and soft attributes that lead to good governance (Edwards & Clough, 2005; Larcker, Richardson, & Tuna, 2004). Ongoing public sector reform has also emphasised that one governance model size does not fit all organisations (Edwards & Clough, 2005; Larcker et al., 2004).

The effectiveness of an organisation's corporate governance strategy can be measured through performance and conformance. Performance describes how well an organisation has achieved its goals. Conformance refers how an organisation behave in accordance with legal requirements, corporate and industry standards, as well as relevant guidelines. These are particularly important elements of an effective public sector governance to ensure that accountability obligations are appropriately discharged (Arjoon, 2006; Barrett, 2002 ; Bridgman, 2006).

Barrett (2002) noted that the public sector is often perceived to be risk adverse because there has been a tendency to focus on ensuring conformance with legal and procedural requirements rather than striving for exceptional performance. He further noted that the sector faces a particular challenge to "strike an appropriate balance between performance and conformance" (Barrett, 2002 , p.1) because all decisions are made within a risk management framework to weigh potential benefits against potential costs.

In effect, the scope of "good" corporate performance and accountability goes beyond the immediate confines of the organisation, but must also recognise the requirements of the broader environment in which it is practiced and the stakeholders it serves.

2.2.3.2 Horizontal and vertical planes. Public sectors involve webs of services, providers, recipients, organisational structures and multiple levels of government. Government directives may be exerted from federal or state level, so the interaction between levels of government influences organisational governance strategy.

The last decades of the 20th century were associated with a fundamental shift in the principles of public sector management in many industrialised countries (Christensen & Lægreid, 2007). Governments have moved away from traditional, hierarchical models of public administration towards a multi-level or integrated approach (Christensen & Lægreid 2006). Multi-level or integrated governance models straddle traditional departmental lines of authority by involving both vertical and horizontal relationships (Australian Public Service Commission & Commonwealth of Australia, 2009).

Multi-level governance involves a notional vertical line which extends from the inner governance of an organisation to those ultimately answerable (i.e. the Commonwealth government) and a notional horizontal line extends between organisations within the same level (Edwards et al., 2012). Vertical dimensions or the linkages between levels of government are critical to the coherence of public policy. Horizontal dimension is important as a means of ensuring comparable service delivery and that strategies are implemented. Integrated governance models can impact greatly on the understanding and use of core corporate governance concepts, such as performance, conformance and accountability (Edwards et al., 2012). Critics have argued that existing reporting mechanisms are designed for vertical accountability. It is difficult to establish horizontal accountability if more than one party are performing the same action (Christensen and Lægreid 2007).

Table 2.1: Summary of Network Evaluation Relationships

Levels of network analysis	Key stakeholder groups	Effectiveness criteria
Community	Principals and Clients Client advocacy groups Funders Politicians Regulators General public	Cost to community Building social capital Public perceptions that problem is being solved Changes in incidence of the problem Aggregate indicators of client well – being
Network	Principals and agents Primary funders and regulators Network administrative organisation' Member organisations	Network administrative growth Range of services provided Absence of service duplication Relationship strength (multiplicity) Creation and maintenance of network administration (NAO) Integration / coordination of services Cost of network maintenance Member commitment to network goals
Organisation/ participants	Agents and clients Member agency board and management Agency staff Individual clients	Agency survival Enhanced legitimacy Resource acquisition Cost of services Service access Client outcome Minimum conflict for multi-program agencies across multiple networks

Reprinted from Do networks really work? A framework for evaluating public-sector organizational networks by H. B. Milward, & K. G. Provan. 2001. *Public Administration Review, 61*(4), p 421)

Table 2.1 presents the findings from a study of multi-level governance in the United States of America (USA) which identified a "hollow state", where a government agency relies on others to deliver a service (Milward & Provan 2000a, 2000b, 2001).The study found that replacement of traditional bureaucratic "command and control" mechanisms by a networked relationships of non-government service providers led to non-aligned effectiveness criteria. The table shows three levels of involvement: community, network and organisational. Each level differs in what they perceive to be the effectiveness of the program, which the authors attribute to self-interest.

In Australia, a whole of government approach provides a platform for government intervention through activities at a lower level of government (Commonwealth of Australia, 2014). Cross-jurisdictional issues of national significance are usually addressed through the Council of Australian Governments (COAG). COAG, the peak intergovernmental forum in Australia, is supported by ministerial-level Councils that facilitate consultation and cooperation between the Commonwealth and the States and Territories in specific policy areas. The aim of the cross-jurisdictional recognition or mutual acceptance is to establish a regulatory environment which encourages national enterprise, enable business and industry to maximise their efficiency and to promote international competitiveness.

The mutual acceptance arrangement facilitated the introduction of the Intergovernmental Agreement on Federal Financial Relations (IGAFFR) in 2008. The IGAFFR established a new framework for the Commonwealth's financial relations with the States and Territories and represented a significant shift in Commonwealth-State relations. Consequently, the impact of COAG strategy has broadened, including impacting the processes by which review for multi-site research is undertaken.

2.2.4 Private and public governance models

Although corporate governance began in the private sector and have traditionally focused on the corporation-shareholder relationship (Edwards & Clough, 2005), public institutions began to adapt governance models at the end of last century. Private and public governance models share many similar values, such as the need for accountability, transparency, honesty or integrity but differences emerge from the context in which they are embedded (Armstrong, Jia, & Totikidis, 2005). While private or non-government business enterprises are intended to earn a profit, the public sector is concerned with such government actions as service delivery, legal and policy development, managing government finance, tax collection and law enforcement. The governance models of private organisations reflect the corporate governance principles and recommendations provided by the Australian Securities Exchange (ASX Corporate Governance Council, 2007), whereas the Auditors General and Public Service Commissioner guide the public sector. Differences in the influences and characteristics of private compared to public sector governance are outlined in Table 2.2.

Table 2.2 Differences between the Victorian public and private sector governance

Governance	Private Sector	Public Sector
Organisation structure	Enterprise: Outsider/insider models	Department Statutory Authority State owned enterprise Private/public partnerships
Regulation	*Corporations Act* 2001(Cth.) (AustlII.) Regulated	Victoria's public health services are independent legal entities established under the *Health Services Act (HSA)* 1988 (Vic) (AustlII); *Public Administration Act* 2004 (Vic) (AustlII); *Commonwealth Corporations Act* 2001(Cth.) (AustlII.) and *State Owned Enterprises Act* 1992 (Vic) (AustlII Statutory legislation Regulator and regulated
Agents	For Shareholders	For Public
Objectives	Profit	Public good
Origin of Governance model	ASX Standards Australia	Auditors General Public Service Commissioner
Authority	Board	Government Minister for Health Department of Health and Human Services Board
Responsibility	Legal Responsibility of board	Responsibility diffused
Independence	Legal Independence of Board selection and appointment of members	Ministerial control
Accountability	To shareholders	Diffuse
Reporting	Annual Report to shareholders	Ministers Parliament Auditor general Agency Heads Treasury and Finance

Adapted from *Parallels in Private and Public Sector Governance* by A. Armstrong, X.Jia, & V.Totikidis, 2005. (p 3) Paper presented at the GovNet Conference, Monash University, and Melbourne.

The implication of the information in Table 2.2 is that equivalent organisations from private and public sectors differ in their compliance obligations, which impact on their organisational autonomy and governance decisions. Public sector governance reflects

the involvement of multiple stakeholders. The impact of Ministerial control and auditing by an Auditor-General imposes further governance obligations.

2.3 Research governance

2.3.1 Definition

Research governance implies a specific subset of corporate governance undertaken by the Board to regulate the research activity undertaken under the auspices of organisation but, even in this relatively limited capacity, different interpretations of the term have emerged.

In Australia, the term "research governance" refers to the activities through which an organisation observes responsible research practices. Guidance for responsible research practices is provided by the National Health and Medical Research Council (NHMRC) (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007). Organisations are expected to establish standards of research integrity and develop a research governance framework to implement the standards.

> Research governance is an organisational framework through which all research (not just research involving humans) meets appropriate standards of quality, safety, privacy, risk management, financial management and ethical acceptability, and through which the relative roles and responsibilities of those involved in research are prescribed (Frew & Martlew, 2007, p.20).

Research governance is also used to describe the tasks involved when a site specific assessment (SSA) is being made of a prospective research project and is undertaken at the same time as the HREC review.

> Research governance considers the legal compliance, financial management, accountability and risk management associated with a participating site. Research governance is administered by the process of site specific assessment (SSA). Research governance/SSA is

> essential in the system for streamlined ethical review of multi-site research projects, and it is also used for single-site research projects (Victorian Department of Health and Human Services, 2016b).

These definitions of research governance are focussed on the organisation undertaking the research, which indicates that the SSA decisions are tied to organisational strategy. In process terms, there is a separation between the activities undertaken for research governance and the ethical review.

> Research governance/SSA is separate from ethics review. Research governance/SSA must occur at all organisations conducting health and medical research. Both ethics approval and research governance/SSA authorisation are required before a research project can commence at a site (Victorian Department of Health and Human Services, 2016b).

In contrast, the goals of the NMA centre on the effectiveness of the process of single ethical review (Victorian Department of Health and Human Services, 2016a). According to current literature, research review of multi-site research requires cohesive practices between relevant entities to ensure the timeliness of multi-site research review, conserve resources and, where appropriate, act as an incentive to attract investment from commercial partners (Clinical Trials Action Group, 2011; Manville et al., 2013; NSW Ministry of Health, 2013; Webster & Temple-Smith, 2013; White et al., 2016). Despite concerns regarding delays in research governance processes, there has been limited discussion on what constitutes research governance in the context of the NMA.

Literature also indicates that conflict may arise when setting organisational standards are based on local issues that conflict with the goals of a national model of common research management (Franck et al., 2004). Definitions of research governance from the United Kingdom (UK) emphasise overall research quality (UK Department of Health, 2005) and literature from the UK observes that research governance:

> … is the system of administration and supervision through which research is managed, participants and staff are protected, and accountability is assured.

> Governance is not the remit of any single institution (indeed, a guiding principle is that it is everyone's business) (Shaw et al., 2005, p. 497).

Shaw et al. continue to observe that the combined responsibility for research governance has highlighted disparity between different parties and codes of practice, laws and professional standards. This supports the observations made by Franck et al. (2004) of probable tensions between the goals of the NMA and the healthcare agencies if the agencies' governance focus remains solely on their own requirements.

Single ethical review in Australia presents a complex and conflicting picture. The timeliness of clinical trial approvals has been identified as a key factor in the development of a strong and unified medical research culture (Clinical Trials Action Group, 2011; Health Outcomes International, 2015; Khan et al., 2013) but the existence of multiple governance practices, as indicated in the comparison of submission practices, presented in Appendix N, suggests persistent focus on indiviual organisational practices.

Research governance within a national review model must recognise the central role of the healthcare agency in ensuring the research integrity but that the overall aim is to enable and efficient national system.

2.3.2 Paradigms of research governance

Governance does not develop in a vacuum, but is contingent on surrounding influences. Research governance, and what constitutes appropriate protection for research participants is not static, but has evolved over time in keeping with the current values of the era. Over time, paradigms shifts in social values, usually catalysed by crises or scandals, have changed how the protection of the research participant was viewed and have forced a re-examination of the existing research oversight arrangements (Gordon & Prentice 2000).

Emanuel and Grady (2006) identified four overlapping paradigms of research and research oversight in the United States since World War II: Researcher Paternalism 1940–Early 1970s; Regulatory Protectionism Early 1970s–Mid-1980s; Participant Access Mid-1980s–Mid-1990s;and Community Partnership Mid-1990s (Emanuel &

Grady, 2006).The paradigms of research governance values reflect the values of the broader community at the time. Although the boundaries of the paradigm periods are not fixed, the authors suggest that that the changes in community values bring about different approaches to research oversight and what is considered to be appropriate protection of research participants (Table 2.2).

Table 2.3: Four periods and paradigms of USA research oversight

	Researcher paternalism	Regulatory protectionism	Participant access	Community partnership
Dates	1940–early 1970s	Early 1970s–mid-1980s	Mid-1980s–mid-1990s	Mid-1990
Triggering event(s)	World War II	Jewish Chronic Disease Hospital Beecher's revelations; Tuskegee Syphilis Study	AIDS epidemic; breast cancer movement	Genetic research among Ashkenazi Jews and aboriginal communities; International HIV/AIDS research
Key protection	Researcher judgment	IRB review and individual informed consent	Individual autonomy	Introduction community collaboration
Conception of subject	A passive "subject" of research	Vulnerable party	Informed consumer	Participant—active participant in research enterprise
Conception of biomedical research	Sharp distinction between care and research		Clinical research is the best type of clinical care	Continuous with clinical practice
Underlying philosophy	Utilitarianism	Principlism	Individual rights-based theory	Communitarianism
Highlighted ethical principle	Social value	Independent review	Informed consent	Collaborative partnership

Adapted from our Paradigms of Clinical Research and Research Oversight by E. J. Emanuel & C. Grady, 2006. *Cambridge Quarterly of Healthcare Ethics*, 16, p.83.

The period of "Researcher Paternalism" started immediately post World War II. In that period, the foremost protection for research subjects was considered to be the integrity of the researcher and the researcher's judgment. This period ended in the early 1970s following a series of research scandals, one of which was the infamous Tuskegee Syphilis Study conducted between 1932 and 1972 into untreated syphilis. The study was

closed due to lack of participant consent and non-disclosure of available treatment, which clearly discredited researcher integrity and judgement in relation to participants' well-being (Alsan & Wanamaker, 2016).

The next period, "Regulatory Protectionism", was based in the belief that biomedical research was inherently dangerous and thus the goal of oversight was to "protect participants from researchers and the inherent risks that they and their research posed" (Emanuel & Grady, 2006, p.88). Decision-making of research acceptability was allocated to independent review groups, government regulators, and research participants themselves. This is the era in which the introduction of ethics committees review and the formalisation of informed consent were now considered the best protective mechanism for research subjects. The USA regulatory system, *Title 45 Code of Federal Regulations, Part 46,* entitled *"Protection of Human Subjects"* which oversees the interests of participants and the ethics of research was codified in 1981 and therefore included in this era.

The cultural and context-bound nature of research rights and oversight is powerfully illustrated in the contrasting position of the third paradigm, "Participant Access" from the mid-1980s to mid-1990s, which addressed the burdens of regulatory protectionism in research. Emanual and Grady argue that drivers of this paradigm shift included the AIDS epidemic and the breast cancer movement. The momentous nature of these diseases coupled with ideas of individualism and the free market, as championed by the Reagan presidency, lead to not only a demand for more research, but also a right for potential participants to "autonomously decide to try risky but potentially beneficial treatments, a right which they claimed should trump regulatory protectionism and paternalism" (Emanuel & Grady, 2006, p.90).

There are many ongoing ramifications of this era such as: perceptions of the participant being perceived as a partner in research and that equitable access should be available to demographic groups (Emanuel & Grady, 2006); as well as regulatory changes to allow access to investigational drug outside the clinical trial setting (Junod, 2014).

The limitations and potential drawbacks of the participant access model began to emerge from three sources: genetics research which engaged families and communities

in order to identify specific genes; research sponsored by developed countries but conducted in developing countries that caused severe disadvantage necessitating community action; and the integration of the earlier activists into research enterprises (Emanuel & Grady, 2006). The Community Partnership era began around the 1990's. Although there is considerable overlap of these paradigms, Emanuel and Grady demonstrate the evolving nature of research governance and that paradigms regarding appropriate practices are influenced by changes in social values and external events.

Since 2006, issues have arisen that were not addressed by Emanuel and Grady and that indicate emergence of a further paradigm shift. Growth of commercial research, especially that involving multiple sites or countries, has accentuated the need for standardisation of research practices world-wide (Health Outcomes International, 2015). Regulatory globalisation and post marketing pharmacovigilance have become more important to the outcome of commercial research which is largely registration of a new product (Demortain, 2015). More recently, there has been a greater involvement of private actors, such as Contract Research Organisations (CROs), used by pharmaceutical companies to outsource research activities, in regulatory arrangements. Concerns raised over bureaucratic delays in research review processes have generated much discussion and consequent restructuring of existing regulatory processes (Manville et al., 2013).

Another critical issue that impacts on the paradigm through which research review is undertaken is the need for integrity of clinical research results. The impact of significant research fraud, although rare, has a profound impact on scientific and business landscapes, especially when publication retractions are required (Zhang & Grieneisen, 2012). In theory, retracting a research publication is tantamount to withdrawing it from the scientific literature. In practice, however, fraudulent findings can remain within a community. This has been exemplified by a 1998 study by, which claimed a link between autism and the measles, mumps and rubella (MMR) vaccine, being credited with the beginning of the anti-vaccination movement. Anti-vaccination movements argue against compulsory immunisation programs for preventable childhood diseases. Although, the associate publication was retracted in 2010, it had received wide publicity especially on the Internet, and is associated with decreased vaccination rates (Kata, 2010).

Research governance involves cultural constructs that are product of particular time, place and competing interests. Growing complexity of the research environment has altered both the sensibilities in relation to acceptable methods and topics of research as well as increased the scope of the research governance considerations. In alignment with guidance outlined in the *Australian Code for the Responsible Conduct of Research* (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007), organisational governance arrangements generally address principles of compliance, research quality and integrity, ethical acceptability, risk management, health, safety and environmental protection, information, monitoring and quality improvement.

Potentially, the NMA challenges the governance strategy of healthcare agencies on a number of levels. In a governance model that focuses specifically on the healthcare agency, the primary emphasis is on managing local issues and meeting the needs and expectations of the organisation's stakeholders. This can lead to considerable variation between healthcare agencies with regard to standards, priorities, and performance objectives.

2.3.3 Research governance in current literature

In current literature, research governance is usually presented as problematic. There is potential for research review processes to focus on administrative tasks, such as completing a form, rather than exploring the nature and context of the project under review, which leads to criticism of obstruction rather than facilitating research. One suggestion is that research ethics reviews should be aligned with the goals of an institution's research governance to provide institutional-level policy decision about managing multi-site research, including issues such as reciprocity (Allen, 2008). Another approach focusses on the need to ensure integrity through accountability, transparency and responsibility through the life of the study (Poustie et al., 2006).

Multi-site researchers have identified that the duplication of effort required to apply at different sites, and the singular processes of different organisations, absorb financial and human resources with no discernible advantage to the project (White et al., 2016). This is particularly difficult for projects classified as low or negligible risk, because there is

no set definition of what constitutes low risk and the same projects may be assessed differently by separate healthcare agencies or even separate personnel (Webster & Temple-Smith, 2013).

Within clinical trials sector, the separation of ethics and governance was introduced to create a more timely review process. However, concerns of inconsistency in both the HREC review and of site specific assessment remain. Furthermore, the development of a national approach to the review of multi-jurisdictional clinical trials within Australia has created new issues around the time and associated costs involved in obtaining separate ethics and governance approvals.

> There is still a reported lack of consistency and transparency in governance approval scope, processes and timeframes, and concern that the current project to standardise clinical trial costs will need to represent "fair market value" for Australia to remain competitive (Health Outcomes International, 2015).

Literature describing the centralised research governance model adopted in the UK identified centralisation as an effective way of maximising research resources but has also recognised that a lack of engagement at the level of participating organisations prevents full realisation (Franck et al., 2004; Howarth et al., 2008).

Potentially, the NMA challenges the research governance strategy of healthcare agencies on a number of levels. In a governance model that focuses specifically on the healthcare agency, the primary emphasis is on managing local issues and meeting the needs and expectations of the organisation's stakeholders. This can lead to considerable variation between healthcare agencies with regard to standards, priorities, and performance objectives. Problems can arise where addressing specific local issues may conflict with the goals of a consistent national model of care and promotion of common national management (Franck et al., 2004).

2.4 Theoretical basis to the study of governance

This thesis investigated the impact of a national model of single ethical review on the research governance of public healthcare decision-making. Corporate governance theory provided a basis to exploring the topic.

2.4.1 Typology of theories of corporate governance

Corporate governance literature is vast and diverse and consequently there are a number of theoretical frameworks that have dominated the study of corporate governance research (Cornforth & Edwards, 1999; Hough et al., 2005; Hung, 1998) which addresses separate aspects of corporate behaviours.

Thus, different theorists have approached grouping governance analysis through many perspectives. Turnbull (1997) looked at theories from political and cultural perspectives. Cornforth (2004) argued from a perspective of how a Board operated, using models of compliance, partnership, co-optation or rubber-stamping. Hough (2005) classified governance theories according to the underlying discipline. Hung (1998) used a typological approach to classify the dominant theoretical approaches to governance .

Hung separated theories into those with an extrinsic influence perspective and those with an intrinsic influence perspective. The extrinsic perspective includes the theories of Agency, Stewardship, Stakeholder and Resource Dependency where the Board determines the action required to meet an objective, such as increasing trade-related performance. In comparison, those theories with an intrinsic influence perspective perceive the Board's governance role to be of conforming to institutional expectation. For example, Institutional Theory addresses how the environment influences the social behaviours of an organisation. Institutional isomorphic theory or Neo-Institutionalism is based on the premise that organisations tend to appear similar to other organisations faced with the same environmental constraints, in order to appear legitimate to relevant stakeholders. Hung's typology of governing theories is presented in Figure 2.1.

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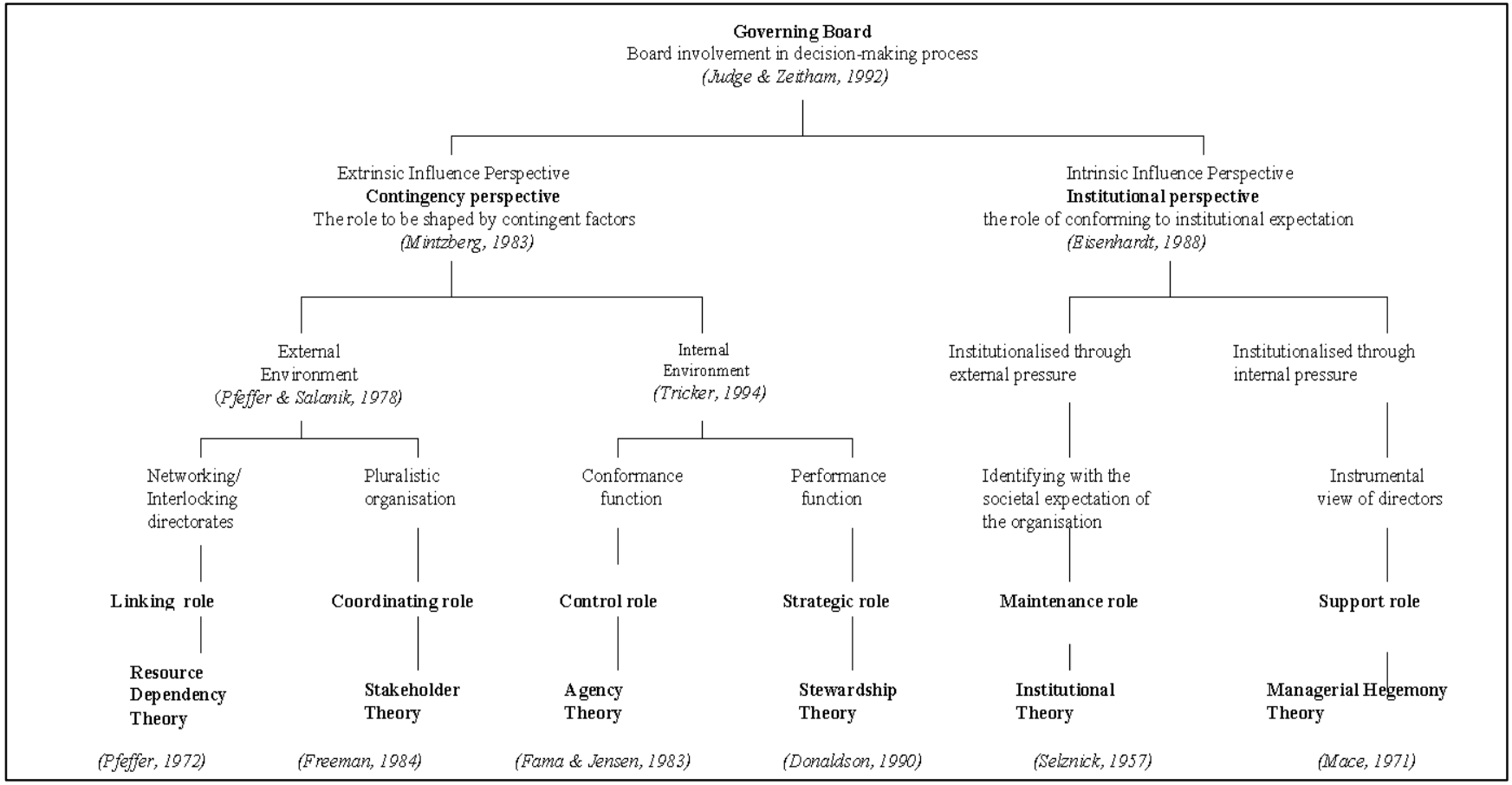


Figure 2.1 A typology of the theories relating to roles of governing boards

(Adapted from A typology of the theories of the roles of governing Boards by H.Hung,,1988, *Corporate Governance: An International Review*, 6:2, p 907)

2.5 Institutional theory

2.5.1 The origins of Institutional theory

Institutional theory explores the deeper and more resilient aspects of social structure. It considers the processes by which processes such as schemes, rules, norms, and routines become established as authoritative guidelines for social behaviour. Thus the theory provides a vehicle to explore not only what has occurred but why organisational elements develop and decline (Scott 2004). There is a rich history to the development of Institutional Theory, incorporating the creative insights of many scholars over many decades

Studies of organisations as a distinctive social phenomenon began to emerge in the 1940's, when the publication by Merton (1948) focussed on the dynamics of social change and presented organisations as independent social actors in modern societal processes. This was directly opposed to earlier research which had treated organisations as a static component of society. Merton proposed that organisational change was brought about through the balance of functional and dysfunctional structures. Weber (1968), another institutional theorist, argued that rationality is the main driving force behind capitalism and industrialization. He explored the institutionalization created by bureaucracy within society and coined the term "iron cage" to depict how increased rationalisation traps individuals in systems based purely on teleological efficiency, rational calculation and control.

Although there was some adherence to traditional explanations of formal structure following the publications of Merton and Weber, institutional theory continued to evolve, shifting focus towards the effects of environmental forces in determining structure. For example, resource dependence proposed by Pfeffer and Salancik (1978) described decision-makers' concerns for maintaining organizational autonomy and power over other organizations. However this approach still retained a rational actor model of decision-making in organisations. The impact of how social influence that might limit autonomous decision-making was largely ignored (Tolbert & Zucker, 1996).

Scott (1987) emphasised the importance of the role played by an organisation's environment and proposed that organisations operate in combination of cultural-

cognitive, normative, and regulative perspectives or pillars. The "three institutional pillars" model (discussed further in Chapter Four) allowed scholars to systematically examine the effects of the institutional environment on discreet areas of organisational activity.

In 1977, Meyer and Rowan published a radical departure from conventional ways of thinking about formal structure by suggesting that organisations have symbolic functional and functional aspects. They proposed that the dependence of social organisations on institutionalised myths defined their core entities, purposes, and interrelationships and through which organisations gain "legitimacy, resources, stability, and enhanced survival prospects" (Meyer & Rowan, 1977, p. 340). Thus, legitimacy gains organisations resources, stability, and enhanced survival prospects. Organisations whose structures become isomorphic with the myths of the institutional environment, rather than being primarily structured for efficiency, may decrease internal coordination and control in order to maintain legitimacy. Institutional theorists exploring the conflict between symbolic and functional requirements fostered the development of three somewhat ambiguous concepts: institutions, legitimacy and organisations.

2.5.2 Institutions

"Institutions" and "institutionalisation" are basic tenets of institutional theory. The institution is the entity to which organisations strive to conform and institutionalisation refers to a social process through which individuals come to accept a shared definition of social reality. The process occurs when values associated with an organisational practice or structure are integrated with areas in social life that are able to sanction or enforce it, such as law or government policy (Colyvas & Jonsson, 2011).

An organisational practice or structure is institutionalised when values associated with it are integrated with areas in social life that are able to sanction or enforce it, such as law or government policy. Institutions have not been definitively defined in institutional theory. Scott has described some of the qualities of an institution, as

> … social structures that have attained a high degree of resilience [and are] composed of cultural-cognitive, normative, and regulative

> elements that, together with associated activities and resources, provide stability and meaning to social life (Scott, 2008, p. 48).

This definition stresses cultural-cognitive, normative, and regulative elements, distinguished because they provide differing bases of social order. Different theories that have emerged about institutions stem from their varying emphasis on a specific institutional element (Scott, 2010).

In summary, institutions provide a mechanism of instilling worth for organisations. The foundation of an institution is shared rules, typification and the associated activities or relationships but to be effective these rules and norms must also be endorsed by a sanctioning authority. Endorsement from the sanctioning authority establishes an organisation's legitimacy.

2.5.3 Organisations and organisational fields

Understanding the organisation as a social mechanism for achieving collective ends has a predominant role in institutional theory. However, over time, definitions of organisations have fluctuated. Weber provided the foundation definition of organisation by describing them as a bureaucracy or goal-oriented organisational structure that is characterised by many rules, standardised processes, procedures and requirements as well as a detailed division of labour, responsibility and hierarchies. He created the metaphor of the iron cage because the bureaucracy is the greatest expression of rationality. In contrast to Weber, contingency theorists claim that there is no best way to organise a corporation, to lead a company, or to make decisions. They argue that the optimal course of action is contingent (dependent) upon the internal and external situation (Scott, 2014b). There is also an argument that definitions of organisations have been neglected as modern theorists have focussed more on understanding of institutional processes (Greenwood, Suddaby, & Hinings, 2002).

Lack of a clear definition of the organisation may have a follow on impact on how study findings should be interpreted. For example, an organisation following Weber's definition would most likely respond en masse. However, if the setting of the organisation was at department level of a larger establishment, it may mean that that legitimacy goals may conflict with competing legitimacy requirements. How the

organisation is defined will also impact on how the organisational field or groups of organisations are viewed.

The concept of organisational field is a useful instrument of analysis for institutional theorists because it provides mechanism of delimiting the boundaries of isomorphic influence. Structurally, organisational fields are defined as "sets of organisations that, in the aggregate, constitute a recognised area of institutional life; key suppliers, resource and product consumers, regulatory agencies, and other organisations that produce similar services or products" (DiMaggio & Powell, 1983, p.148). From this perspective, an organisational field involves the totality of relevant actors who share systems of common meanings and interact more frequently among themselves than with actors from outside the field. Organisations are structured into a field through competition, the state or by profession (DiMaggio & Powell, 1983).

Fields can also be based on purpose or meaning. For example, Scott and Meyer (1991) defined organisational fields as a functionally specific arena that includes many different but interdependent organisations. In this approach, a functional organisational field is a set of "similar and dissimilar interdependent organizations operating in a functionally specific arena together with their exchange partners, funding sources and regulators" (Scott 2004, p. 9).

Further authors have highlighted an organisational field as: a centre of dialogue and discussion (Hoffman, 2001); a network of relationships (Powell, 2007); and as a structuration process, involving both the creation and reproduction of social systems based on structure and agents (Machado-da-Silva, Guarido Filho, & Rossoni, 2006).

These different definitions suggest that the concept of organisational fields is context driven, implying a synergy between the field entities and why the field developed in the first place. This, in turn, suggests that fields themselves may be dynamic, shifting to create new realities depending on the pressures from the environment and that delimitations of an organisational field may be weaker or stronger depending on the organisation's investment in that arena.

2.6 Legitimacy

2.6.1 What is legitimacy?

Legitimacy has long been recognized as "a core element in political and governance regimes, dealing with the relationship between societal acceptance of regimes and institutions and their ability to exercise power and authority effectively" (Brinkerhoff, 2005, p. 1). In order to function effectively, organisations must conform to the prevailing rules and belief systems in their environment (DiMaggio & Powell, 1983) Complying with pressure to be similar to others within a specific organisational field makes the organisation appear legitimate (Deephouse, 1996; Suchman, 1995).

The concept of legitimacy is central to Institutional Isomorphism, because it provides the goal to which organisations facing similar environmental constraints aspire. Legitimacy encompasses normative, legal, sociological, and cultural meanings so that definitions of organisational legitimacy are relatively broad and vague. Frequently cited definitions of the term include:

> Organizational legitimacy refers to the degree of cultural support for an organization—the extent to which the array of established cultural accounts provide explanations for its existence, functioning, and jurisdiction (Meyer & Scott 1983, p. 201).
>
> Legitimacy is a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions (Suchman, 1995, p. 574).
>
> Legitimacy is not a commodity to be possessed or exchanged but a condition reflecting cultural alignment, normative support, or consonance with relevant rules or laws (Scott 1995, p.45)

As a social construct, legitimacy is based on a reaction of observers to their perception of the organisation. According to Meyer and Rowan (1977), as social processes, obligations and actualities become commonly accepted, they take on a rule-like status in social thought and action. Hence, within institutional theory, legitimacy provides the primary incentive for the adoption of institutionalised practice in order to provide

stability in the face of uncertain markets or changing technologies (Meyer and Rowan, 1977).

By recognising legitimacy as a social construct rather than a specific designation, these definitions have led to significant debate in the "understanding of the dimensions, subjects, and sources of legitimacy, as well as of the processes, antecedents, and consequences of legitimation" (Deephouse & Suchman, 2008, p.52). Legitimacy and processes of legitimation are phenomena that develop and function externally to an organisation. Legitimation or legitimisation refers to the process of providing legitimacy by confirming something as acceptable and normative to a group or audience of stakeholders. However, within the complexity of a modern healthcare agency, these social constructs may have multiple dimensions and different stakeholders may have diverse legitimacy goals of the same situation.

Suchman and Deephouse state that formally defining legitimacy leads to "understanding of the dimensions, subjects, and sources of legitimacy, as well as of the processes, antecedents, and consequences of legitimation" (2008, p.52). The inference is any quantification of legitimacy may be contextual rather than perceived the same by all stakeholders (Deephouse, 1996).

2.6.2 Dimensions of legitimacy

Both Scott and Suchman identified more than one dimension of legitimacy. Scott listed regulative, normative and cognitive dimensions that linked to three pillars of institutions (Scott 1995). Suchman (1995)combined three dimensions (pragmatic, moral, and cognitive) with two temporal textures (episodic versus continual) and two foci (organisational actions versus organisational essence) to create twelve distinct legitimacy types: pragmatic legitimacy which encompasses exchange, influence, and dispositional legitimacy; moral legitimacy which includes consequential, procedural, structural, and personal legitimacy; and cognitive legitimacy which reflects a taken-for-granted element comprising of predictability, plausibility, inevitability and permanence (Deephouse & Suchman, 2008; Suchman, 1995).

A summary of different dimension of legitimacy, adopted from the works of Brinkerhoff (2005) and Deephouse & Suchman (2008), has been provided in Table 2.4.

Table 2.4: Types of organisational legitimacy

Type	Definition	Legitimacy types	Relationship with constituents
Normative (moral) legitimacy	Organisation reflects acceptable and desirable norms, standards, and values.	Consequential, procedural, structural, and personal legitimacy	Organisation meets normative judgments about outputs/results, procedures and technologies, structures, leaders and personnel.
Pragmatic legitimacy	Organisation fulfils needs and interests of its stakeholders and constituents.	Exchange, influence, and dispositional legitimacy	Organisation exchanges goods and services that constituent want, and receives support and legitimacy.
Cognitive legitimacy	Organisation pursues goals and activities that fit with broad social understandings of what is appropriate, proper, and desirable.	Predictability, plausibility, inevitability and permanence	Organisation "makes sense" and/or is "taken for granted" according to socially construct "realities."

Adapted from Brinkerhoff (2005) and Deephouse & Suchman (2008) by the author

Pragmatic, moral and cognitive legitimacy may co-exist in real world settings although they are conceptually distinct. As an example, pragmatic legitimacy rests on audience self-interest or on individual utility calculations but both moral and cognitive legitimacy require cultural frameworks. Consequently pragmatic legitimacy might be gained through offering tangible rewards to stakeholders but this would be unacceptable in moral and cognitive terms. Similarly, both pragmatic and moral legitimacy rest on discursive evolution whereas cognitive legitimacy, whose implicit taken-for-granted base, may be threatened by public discussion (Deephouse & Suchman, 2008; Suchman, 1995). The identification of more than one dimension of legitimacy that may concurrently coexist also suggests that perception of the same legitimacy issue might be contextual or viewed differently by different stakeholders (Deephouse, 1996).

2.6.3 Managing corporate legitimacy in complex environments

Organisation often face dynamic but fragmented operational environments which comprise of diverse and, often, contradictory demands. Within this environment, organisations may also need to be cognisant not only of their legitimacy goals as a single entity, but how those goals apply to a member of a broader setting, such as a supply chain or a network or group. Issues of capacity and performance remain central but

organisations need to consider needs of peers as well as their own. Thus, what constitutes capacity, how to build and retain it, where capacity resides or with whom, and how to measure the translation of that capacity into performance are all issues raised in debates regarding any system that crosses areas of responsibility.

There is a growing body of socio-environmental literature regarding the management of corporate legitimacy in complex environments. Panarchy theory, for example, describes evolving hierarchical systems with multiple interrelated elements (Stange, Ferrer, & Miller, 2009). Within this system, each level operates at its own pace, invigorated from below by faster, smaller cycles of innovation but protected from above by slower, larger levels. Panarchy is, therefore, a logical partnership between creative and conserving (Holling, 2001). In contrast to standard hierarchical models, which assume system control from the higher to lower levels, panarchy integrates theories of resilience, adaptation and learning at all levels (Stange et al., 2009).

Many theorists have examined the public health sector and the non-linear nature of change (Diut & Galaz, 2008) that require organisations to adopt different organisation behaviours, such as moving away from institutional specific governance to an integrated approach. Traditionally, hierarchical government models have dominated public sector service delivery. However, such rigid structures have not been able to meet the demands of issues related to societal complexity, diversity, and dynamics, thus opening the way for different governance modes to emerge. An alternative approach is for the government to influence the strategies of the public health organisations through agreements with chief executive officers, who then re-align managerial tasks in keeping with strategy.

However, socio-environmental theorists argue that such re-alignment needs to recognise existing institutional practices that may well act as a brake or protection. Struggles between centralised strategies and the needs of individual organisations are increasingly common in public sectors (Butcher, 2015; Diut & Galaz, 2008; Eggers, 2008; Kooiman & Jentoft, 2009).

Re-alignment of managerial tasks away from the traditional measureable tasks as has led to the development of a ‘soft’ governance approach to policy implementation. Soft

governance is where government relies less on hierarchy than on information to steer local organisations, using a combination of formal accountability and professional autonomy (Brandsen, Boogers, & Tops, 2006). In order to retain local flexibility, governments may use advisory guidelines rather than official directives. The problems with unofficial guidelines is twofold. They can become problematic if they are deemed as official and included within formal mechanism of accountability, because they may become too rigid and insensitive to local situations (Brandsen et al., 2006). Alternatively, as local organisations cannot be forced into compliance, their non-adherence can destabilise the central strategy.

The literature shows that managing legitimacy goals in a complex environment is not straightforward. Socio-environmental literature emphasises the fluidity of broader environments and the non-linear nature of change that require organisations to adopt different organisation behaviours including involvement of hierarchies and adaptive cycles. As discussed, organisational legitimacy in its various guises (normative, pragmatic, and cognitive) originates from judgments made by observers of organisational attributes, qualities, and achievements (Brinkerhoff, 2005; Deephouse & Suchman, 2008).

In order to promote its acceptability within a complex environment to its stakeholders, organisational activities related to legitimacy fall within the dynamic of aligning the organisation with its surroundings. For the public sector, perceptions of an organisation's legitimacy also focus on meeting government expectations as well as those connections with other stakeholders.

2.6.4 Legitimacy of single ethical review within public health

The issues outlined above regarding the difficulties of establishing legitimacy in a complex environment is exemplified by single ethical review in the public health sector. Public health care is characterised by many autonomous yet interdependent actors, including: agencies and associated workers; government bodies; suppliers of drugs and equipment; academic associates and peers; as well as consumer advocacy groups; political representatives and political parties; insurers and payers; regulators and accreditors; professional associations; the legal system; information technology vendors

and many, many others (Dixon-Woods & Pronovost, 2016). How this complexity should be addressed depends on the perspective of the stakeholder. Policy makers and funders, for example, perceive the way forward through public policy and economic constraints whereas clinicians and patients feel that clinical or patient-centred strategies are the means to achieving a desired outcome (Sturmberg, O'Halloran, & Martin, 2012).

Public health operates within highly institutionalised environments. The major pressure on healthcare agency behaviour is exerted through government funding agreements that address specific healthcare targets (See Victorian Department of Health, 2013b). Since the 1990's, there have been strong macro-economic reform and national productivity drivers reflecting the many aspects of healthcare and the socio-political agenda for management (Bennett, 2013; Loewenson, 2008). Within this context, the majority of healthcare reform has been driven by government and focussed on performance of clinical services.

Healthcare research has an uneasy relationship with clinical care. The nature of clinical research, while appearing similar to interventional clinical care, is experimental and falls outside standard care. Additionally, while biomedical research has long been viewed as having a high value to society by providing important information about disease trends and risk factors, outcomes of treatment or public health interventions, functional abilities, patterns of care, and health care costs and the utilisation of services (Nass, Levit, & Gostin, 2009, p. 21), deliverables in health care research, especially within a short term, are often difficult to quantify. Completion of the life cycle of a research project, for example, may take several years and involve stages, such as laboratory work or literature searches, that may not directly connect with patient outcome.

Operational responsibility for research falls to the organisation undertaking the research. Traditionally, this has included reviews for scientific and ethical integrity as well as the organisational capacity to perform the project. Multi-site research and single ethical review challenge this proprietary model, through the introduction of project goals and objectives outside the auspices of the organisation. Thus, as observed by Deephouse (1996), the legitimacy of single ethical review may be viewed differently by different stakeholders.

2.7 Institutional Isomorphism

DiMaggio and Powell (1983) provided another dimension to the dynamics of social change by asking why organisations facing the same environmental constraints develop similar characteristics. This was not a new consideration. Weber (1968) had argued that competitive forces in society pressured organisations to develop similar structures and processes and Scott (2014a) described how regulative activities such as rule-setting, monitoring and sanctioning of activities result in standardised behaviours. Institutional isomorphism was distinct from these perspectives in "its assertion that organizations became similar not through adaptation to an external or technically demanding environment or through the 'weeding out' of technical and social misfits, but through adaptation to a socially constructed environment" (Boxenbaum & Jonsson, 2008, p.3).

Institutional Isomorphism is a particular stream of institutional theory that focuses on isomorphism and organisational legitimisation. The term "isomorphism" describes how dynamic social forces prevail on organisations that inhabit similar environments to adopt similar structures and behave in similar ways (DiMaggio & Powell, 1983). This theory creates an alternative to functional and rational explanations of organisational forms by pursuing an understanding of similarity and stability within organisational fields (DiMaggio & Powell, 1983; Meyer & Rowan, 1977; Scott, 1987).

DiMaggio and Powell (1983)are widely regarded as the dominant formative theorists in Institutional Isomorphic theory by their address of the structures that support institutionalisation, coercive, normative, and mimetic isomorphic mechanisms. They argue that institutions tend towards similar development through isomorphism, which they define as a "constraining process that forces one unit in a population to resemble other units that face the same set of environmental conditions" (p. 149). The theory maintains that executive decision-makers "consciously or unconsciously adopt according to coercive, mimetic, and normative processes. The resulting convergence leads to homogenization" (Bailey, 2012, p.109).

Institutional isomorphism theory proposes that the three isomorphic processes stem from different conceptions of how behaviour diffuses, leading to the endorsement of distinct stakeholders. Recognition of legitimacy may vary depending on the audience (Deephouse, 1996). This process is demonstrated in Figure 2.2.

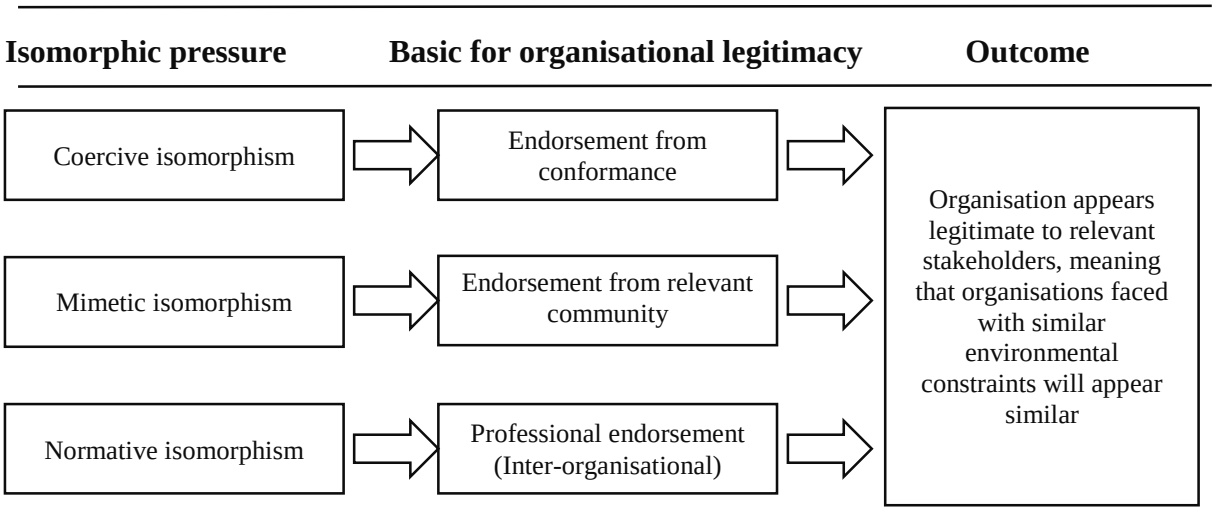


Figure 2.2: Social construction of isomorphic processes leading to homogeneity

2.7.1 Coercive isomorphism

Coercive isomorphism results from both direct and indirect pressures exerted on firms by other entities upon which organisations are dependent, and by the expectations of the societies in which the organisation operates (DiMaggio & Powell, 1983). One such coercive force is the government, through such mechanisms as regulation and legislation; purchasing of goods and services; control of resources; and fiscal policy. Coercive forces have long been seen as driving public sectors through political and budgetary pressures. Public service organisations are directly dependent on government funding and thus are required to react to changing policies and pressures to improve public services as instruments of government policy implementation (Caemmerer & Marck, 2009).

The structures and strategies of public organisations have attracted substantial research attention among public management scholars. Tolbert and Zucker (1996)found that coercive pressures were more effective than mimetic pressures in spreading a new practice. Public sector organisations are vulnerable to all three isomorphic pressures and

coercive pressure encouraged organisations to converge on a middle ground. Agencies subject to outside coercive scrutiny, evaluation, and regulation were found to be more decentralised, less formalised, and less departmentalised than those that were not subject to such pressures (Frumkin & Galaskiewicz, 2004).

2.7.2 Mimetic isomorphism

Isomorphic pressures can also develop because organisations are inclined to model themselves on others which they deem to be successful and legitimate (DiMaggio & Powell, 1983). In contrast to coercive isomorphism, where external forces oblige organisations to change, or normative isomorphism, which develops from professional standards or networks, mimetic isomorphism develops from pressures to copy or emulate other organisations' activities, systems, or structures, especially under conditions of uncertainty. Mimetic isomorphism involves decision-makers deliberately making an effort to obtain information about other organisations in contemplation of imitating their behaviour (Villadsen, Hansen, & Mols, 2010).

DiMaggio and Powell (1983) contend that uncertainty is a powerful force that encourages imitation. If organisational leaders find that a clear course of action is unavailable, they may decide that the best response is to mimic a peer that they perceive to be successful. The organisation being mimicked may not be aware that it is a target for copying. An example of mimetic behaviours is benchmarking, which involves comparison of an organisations processes and performance to those from other organisations. Field level homogeneity among organisations can develop as they adopt the most successful behaviours. Mimetic behaviours are also resource efficient, yielding a viable solution in an uncertain environment with little outlay of the mimicking organisation (DiMaggio & Powell, 1983). Mimetic isomorphism is strongly supported in literature, especially in relation to managers in the public sector.

Studies have found that government agencies are particularly susceptible to mimetic institutional pressures. Frumkin and Galaskiewics (2004) found that government agencies affected by mimetic isomorphism tended to become more centralised, formalised, and departmentalised.

Yang (2006) explored driving factors behind the spread of USA job-training programs. He found governmental agencies to be more responsive to mimetic institutional influences than non-government because they are in greater need of external legitimation of their procedures and operations. He also observed that mimetic impact was cumulative and as more organisations joined the activity, the more likely an organisation was to adopt such programs.

Villadsen et al. (2010) undertook a survey of Danish municipal public managers facing important and complicated contracting decisions to examine mimetic decision-making in relation to different types of uncertainty. Mimetic pressure was most strongly associated with technological uncertainty and there was no significance associated with either volume uncertainty or performance uncertainty. The authors concluded that uncertainty, through mimetic decision making, is connected to organisational isomorphism and highlighted need for research into the multi-dimensionality of uncertainty and its consequences.

Not all mimetic pressures exert a positive effect on an organisation's productivity. A USA study of whether peer influence is sufficient to overcome a product evaluation indicated senior information technology and business decision-makers were likely to choose inferior technologies if respondents were informed that competitors had selected them (Tingling & Parent, 2002). Other studies support dominance of the need to demonstrate legitimacy in business decision-making. Barreto and Baden-Fuller (2006)studied Portuguese bank branching decisions between 1988 and 1996 and found that study subjects set up new branches in locations that were both attractive and not attractive to their business. They concluded that these results show the tension between the pressure to conform, the pressure to perform and the importance of the influence of legitimacy on organisational decisions. Campion and Gadd (2009)noted that results of local pilot site studies may have encouraged other hospital units to adopt the care change, despite not fully understanding the effects.

Literature supports the suggestion that mimetic isomorphism develops from pressures to mimic other organisations especially under conditions of uncertainty. However, the studies outlined above also suggest that the drive towards appearing legitimate may negatively impact an organisation's productivity.

2.7.3 Normative isomorphism.

Like the isomorphic influence from coercive pressures, normative isomorphism develops externally to the organisation. It "stems primarily from professionalization – the collective struggle of members of an occupation to define the conditions and methods of their work … as professions are subject to the same coercive and mimetic pressures as organizations" (DiMaggio & Powell, 1983,p. 152).

As a discipline evolves, normative pressures develop as its participants seek to distinguish what they do from what others outside the field do. DiMaggio and Powell (1983) identified two processes within professionalisation. Firstly, professionals are socialised into similar world views through similar training (membership). Secondly, inter-organisational networks that span organisations provide important vehicles to disseminate information of institutional norms and behaviours amongst a professional community (procedure). Thus, ideas diffuse through the networks professionals develop through practice societies, educational activities, and common knowledge bases. This suggests that professionals work autonomously, and that, in times of uncertainty would refer to professional circles rather than organisational controls.

Teodoro (2014) argued that executives who belong to a specific profession ought to manage differently from similarly situated executives who do not. The study analysed the degree to which local government water utilities in the USA complied with US Safe Drinking Water Act 1974 (SDWA). Using normative isomorphism as a theoretical base, he described how utilities that were led by engineer executives were more likely to comply with the Act than non-engineer executives. He attributes the difference in executive approach to the professional norms of the engineering profession.

2.8 Weakness in the Institutional Isomorphism approach

Since DiMaggio and Powell, empirical studies have re-examined the related propositions of institutional isomorphism, arguing that the interrelation between policy instruments and isomorphic mechanisms is not simple or straightforward.

2.8.1 Theoretical ambiguity

However, scholars, including DiMaggio and Powell (1983) have highlighted concerns regarding the difficulty of empirically separating isomorphic influences. Mizruchi and Fein (1999) observed the potential for crossover with other theories such as resource dependence (Pfeffer & Salancik, 1978) and that quantifying the separate isomorphic processes have led to ambiguity in interpretation of some findings. They noted that mimetic isomorphism was disproportionality represented in literature but that some scholars had involved the use of mimetic isomorphism in cases where coercive and or normative isomorphism were plausible explanations. Results were potentially interpretable in terms of one or another alternative process.

Ashworth et al. (2007) described a government strategy which capitalised on the three processes. Organisation change in the form of legislation introduced a mandatory duty to develop corporate strategies, review functions, and set targets (coercion). Mimicry was encouraged through the formation of benchmarking clubs and recognition of best performance. Normative pressures were encouraged through networking of program participants. The overall intent was for participants in the change to communicate with each other and share their practices in order to achieve the specific target.

The findings of Caemmerer and Marck (2009) who studied the impact of isomorphic pressures on the development of organisational service orientation in UK public services also revealed influence from coercive, mimetic and normative isomorphism. They concluded that the influences are interlinked and paradoxical, in that they can provide positive and negative outcomes.

2.8.2 Isomorphism as a causal link to organisation behaviour

Rather than an assumed causal link between institutional constraints and the development of organisational homogeneity, institutional impact may depend on how well it fits with the internal context and work environment issues of the organisation. Boxenbaum & Jonsson (2008) analysed publications in institutional isomorphism, noting that, over time, the literature shows a greater recognition of heterogeneity in the institutional environment and in organisational response to institutional pressures. They observed the potential for conflation of isomorphism and diffusion studies and the need

to differentiate between diffusion and institutionalism in their impact on isomorphism1. In the model proposed by DiMaggio and Powell, diffusion was viewed as mechanism that led to isomorphism but Boxenbaum and Jonsson observe that later publications have emphasised isomorphism as a driver of diffusion. This has weakened the empirical evidence from institutional isomorphism studies. Greenwood, Hinings, and Whetten, (2014) also suggest that institutional scholarship has weakened by refocussing away from exploring the organisation as a social mechanism towards explaining institutions and institutional processes.

2.8.3 Decoupling

Decoupling refers to the creation and maintenance of gaps between formal policies and actual organisational practices. Myer and Rowan suggested that decoupling may derive from contradictions with internal organisational efficiency but also conflicts among multiple institutionalised pressures. From this perspective decoupling provides a pragmatic response to conflicting pressures to ensure both legitimacy and technical efficiency (Boxenbaum & Jonsson, 2008).

However, decoupling an organisations core activities from an expected organisational compliance program can also present as a dynamic between the appearance of legitimacy and institutionalised misconduct (MacLean & Behnam, 2010). Decoupling from formal compliance programs can provide particular challenges. In public sectors, compliance programs form the basis of quality assurance in the services provided. They signal that the organisation is in alignment with government expectations. This also means that the collection of service data will provide a trustworthy basis to further government decision-making.

The literature indicates the potential for decoupling in the introduction of national systems into public sectors because of conflict with pre-existing practices, regional, national or international codes of practice; legal and regulatory requirements and

[1] In organisational sociology, the concepts of diffusion and institutionalisation are core concepts, as both processes unfold at the intersections of organisational relations and structures, as well as persistence and change. Both concepts can be widespread, conventional and appropriate but institutionalisation involves a shared definition of social reality where the associated values are sanctioned such as through law or government policy (Colyvas & Jonsson, 2011).

professional standards, norms and values (Ashworth et al., 2007; Franck et al., 2004; Howarth et al., 2008; Shaw et al., 2005).

This literature suggest that despite public healthcare agencies being highly dependent on government support and funding for their survival, the impact of isomorphic influence is not straightforward. The move by governments away from hierarchical models towards a multi-level or integrated approach that involves all levels of government, as noted in section 2.2.3, may also weaken reforms based solely on the rational context of coercive pressures

2.9 Why use institutional isomorphism theory in this discussion of the NMA?

Despite the numbers of criticism that the theory of institutional isomorphism has generated, it provides a useful framework to examine situations where homogeneity should be occurring within an organisational field. For example, the federalism of Australian states and territories crates challenges for inter-jurisdictional government strategy. Although, the presence of multiple bureaucratic players in research review and the notion of national consistency have had a persistent presence in research dialogue (Commonwealth of Australia, 1996; Pittman, 2007), Australia, unlike many other countries, does not have a central research authority able to compel the behaviour of healthcare agencies (Breen, 2005a). The implementation of single ethical review in the public health sector has been an evolving process, both in a cultural and political context. This evolution has raised questions on what are the appropriate research governance practices in a national model and of how to create harmony in a fragmented institutional environment. Institutional isomorphism offers a framework of differentiating between social influences while focusing on a common goals of a single system

2.10 Summary

Chapter Two presented a discussion of the current literature regarding corporate governance followed by a discussion on research governance. It then provided a critical analysis of Institutional Isomorphism theory and its application to contemporary Victorian public healthcare agencies.

Corporate governance involves a number of inter-related and mutually supportive components that centre on creating organisational transparency, responsibility, and accountability within an effective risk management framework. Similarly, research governance has also focussed on organisational responsibilities that ensure the integrity of research performed under their auspices.

In Australia, the term research governance may refer to the activities through which an organisation observes responsible research practices. Research governance is also used to describe the tasks involved when a site specific assessment (SSA) is being made of a prospective research project and is undertaken at the same time as the HREC review. Research governance, as a subsection of corporate governance, has very specific constraints around the ensuring the integrity of research and responsible research conduct in that organisation where the research is being performed.

The NMA challenges the concept of agency specific governance. In a governance model that focuses specifically on the healthcare agency, the primary emphasis is on managing local issues and meeting the needs and expectations of the organisation's stakeholders. This can lead to considerable variation between healthcare agencies with regard to standards, priorities, and performance objectives. Difficulties can arise where addressing specific local issues may conflict with the goals of a consistent national model of care and promotion of common national management.

Institutional Isomorphism provided the theoretical foundation in this thesis and was used to explore influences of public healthcare agency commitment to a national system. This theory centred on the tendency for organisations from similar environments to adopt similar behaviours and practices (isomorphism). Isomorphism is driven by the obligation of organisations to demonstrate their legitimacy to relevant stakeholders, rather than increased productivity. The theory involves three distinct but interconnected isomorphic influences: coercive, mimetic and normative. Literature has found that government organisations are susceptible to isomorphic influences and that perceptions of an organisation's legitimacy may depend on the audience.

Chapter Three introduces the context in which the study was undertaken. Although the data for the study focused on how Victorian public healthcare agencies engaged with the NMA, an aspect of government initiative to attract clinical trials to Australia, the influences on this association range from global research trends to organisational specific. The challenges to the introduction of an Australian national model of single ethical review are discussed before a model to evaluate the effectiveness of research governance is presented.

CHAPTER THREE: THE STUDY CONTEXT

3.1 Introduction

Public healthcare is a labyrinth of service provision, public and private service providers, academic links, consumer representation, commercial interests, regulatory bodies, accreditation agencies and multiple other entities. In this thesis, the term "healthcare agency" is used in to denote a public healthcare entity that is governed by a Board of Directors which is accountable to the Minister for Health for the performance of that health agency. The term "agency" rather than "service" implies a governance instrumentality that extends into a philosophical terrain outside patient services and financial stewardship.

Chapter Three examined the connection between the National Mutual Acceptance (NMA) scheme, a component of the Australian government's strategy to remain internationally competitive in attracting international clinical trials, and the research governance practices of Victorian public healthcare agencies.

In Australia, it is estimated that around 1000 new clinical trials are commenced annually by pharmaceutical, biotechnology and medical device companies representing a $1 billion investment (Australian Government & The Australian Trade and Investment Commission, 2017). It has been estimated that more than 18,000 Australians annually participate in clinical trials sponsored by the medicines industry (Medicines Australia, 2011). The majority of the trials are undertaken at multiple research sites in order to expedite data collection. Many trials involve international sponsors and data is collected from multiple counties. In order to remain a competitive host in the global market, the Australian Government, in partnership with industry and other stakeholders, is implementing a series of reforms to create an optimal clinical trial environment.

For commercial clinical trials, timeliness of the trial "start-up" or commencement is a critical factor in maximising the period of commercial returns. The lack of timelines of research approval has been identified as a significant disincentive to investment (Campion & Engwall, 2013; NSW Ministry of Health, 2013). The clinical trial industry

has been a major influence on regulatory reform of the bureaucratic processes around research review.

The study context presented in Chapter Three reflects the landscape in which single ethical review takes place, and is organised as follows. Sections 3.2, 3.3 and 3.4 presents global research trends, the regulatory landscape and international harmonisation respectively. Section 3.5 describes the move towards single ethical review while Sections 3.6 and 3.7 describe the Australian experience. Section 3.8 then presents research governance and single ethical review. Section 3.9 outlines four measures of research governance. The chapter concludes in Section 3.10.

3.2 Global research trends

Increasingly multi-site approaches are being used to facilitate clinical research data collection. The trend is most clearly documented for commercially sponsored, clinical trials of drugs or medical devices (U.S. National Institutes of Health, 2017), although literature also indicates that the multi-site trend includes other types of research (Driscoll, Currey, Worrall-Carter, & Stewart, 2008; Gold & Dewa, 2005; White et al., 2016). The rise of multi-site research and the concerns that have arisen regarding the difficulties of multiple ethics reviews undertaken by each participating site have pressured decision makers into reviews of their existing regulative processes. Most countries involved with multi-site research have now adopted a streamlined or single ethical review approach (Manville et al., 2013). In this process, research governance has moved away from a sub-section of responsibilities of the reviewing ethics committee into a separate discipline associated with the institution undertaking the research.

3.2.1 Evidence based decision-making

Evidence based decision-making has an important role in public healthcare, which has multiple stakeholders and competing demands for limited funds. This approach uses methods that are based on a positivist paradigm as a "means to critique the natural sciences and researchers espousing a scientific model within the social sciences" (Broom & Willis, 2007, p.19). A positivist approach assumes that reality is constant and concrete and that objectivity is achievable. Thus it can be quantified and measured,

which is very useful in assisting evidence-based health care decisions where there are diverse stakeholders.

Accordingly, the evidence hierarchy (Figure 3.1) ranks research types, based on the rigour (strength and precision) of their research methods, to quantify the quality of study evidence and the risk of bias. The most reliable evidence comes from data aggregated from more than one study. Of the non-aggregated studies, the randomised control model provides the strongest evidence of causation because they "(1) produce study groups comparable with respect to known and unknown factors, (2) remove investigator bias in assignment of patients to groups, and (3) guarantee that statistical tests will have valid significance levels" (Weinberger et al., 2001, p.627).

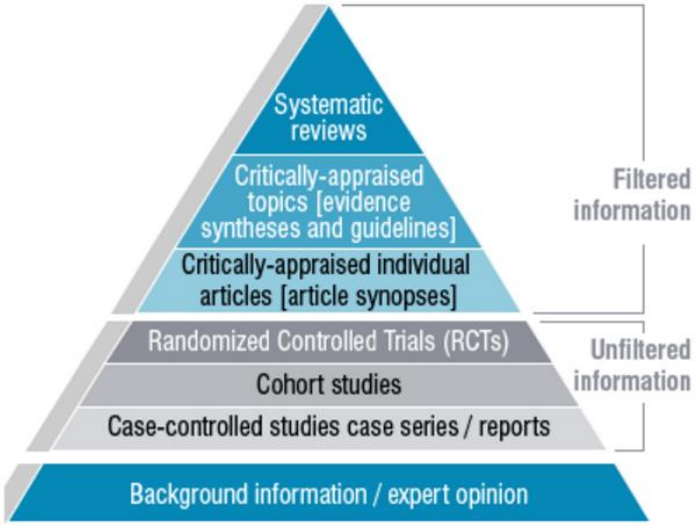


Figure 3.1: Evidence based hierarchy

Reprinted from *Evidence-Based Practice in Health*, 2016. Retrieved from

http://canberra.libguides.com/content.php?pid=591487&sid=5015301

Within this model, randomised clinical trials take precedence over research into treatment effects, and are generally seen as the "gold standard" in providing medical evidence (Weinberger et al., 2001). The randomised clinical trial model provides the platform through which new pharmaceutical products and medical devices are evaluated.

3.2.2 Multi-site research

Multi-site approaches to research offer a number of advantages, such as the ability to collect large amounts of data quickly and the ability to synchronise data when incidences of the item of interest are relatively rare. Large data collections through multi-site studies enhance the external validity of the study, increasing the generalizability of research results (Weinberger et al., 2001). Weinberger et al. further observe that faster recruitment, and thus completion, has a further advantage in health services research, where healthcare decision-makers may be reliant on the timeliness of study findings.

3.2.3 Clinical benefits of clinical trials

Health care decision-making requires an optimal level of evidence to inform diverse clinical and non-clinical stakeholders on a treatment. Clinical trials provide a mechanism through which innovative pharmaceutical drugs and medical devices are evaluated. More than 18,000 Australians are thought to annually participate in clinical trials sponsored by the medicines industry (Medicines Australia, 2011). Proponents of clinical trials describe the potential for clinical trials to provide access to pioneering treatments and technology not yet available in the clinical setting and that may be more effective than standard care approaches. Clinical trials can also provide a key research tool for advancing medical knowledge and clinical care (Clinical Trials Action Group, 2011; Medicines Australia, 2011).

3.2.4 Economic advantages of commercial research

The costs required for drug and device development largely prohibits government and non-commercial funding sources from underwriting the financial sums required to bring innovative products to market. Globally, commercial investment in research and development has been estimated at U.S. $1.6 trillion and attracting commercial investment has become very competitive (Battelle, 2014). Within Australia, it is estimated that the medicines industry invests over AU $1 billion in research and development every year and over 14,000 people are directly employed in the sector (Research Australia, 2011).

High quality clinical trials requires investment in not only facilities and human resources at the organisational level but in the enabling infrastructure. Australia, for example, developed the national Clinical Trials Notification (CTN) scheme to expedite the acceptance of a marketing application for new entity by the Therapeutic Goods Administration (TGA) (McEwen, 2007). Thus, there is financial pressure, both at the organisational level and within the broader landscape, when clinical trials are conducted within a healthcare system.

The most common motivations for participation in clinical trials are to receive high-quality, innovative medical care and contribute to scientific knowledge which enhances the uptake of new evidence into clinical practice (Medicines Australia, 2011). Studies of the economic benefits involved in clinical trials reveal cost-savings through better health outcomes and cost-avoidance. Cost avoidance occurs through provision of a drug therapy and when, during trial participation, costs for standard treatments or testing are absorbed by the trial sponsor, in return for access to the participant's health record data. Health expenditure savings are especially evident for trials involving high cost oncology agents, endocrine and metabolic agents, and neurologic drugs (Shen et al., 2011).

The financial advantage to participating in commercial clinical trials, has pressured many countries, of which Australia is one, to recognise the importance of creating an accommodating environment for clinical trials (Campion & Engwall, 2013; Manville, Hackett, Gunashekar, & Morgan Jones, 2013). In 2011 the *Clinical Trials Action Group (CTAG),* an initiative of the federal government, released a report in which 20 recommendation were made, mostly aimed at making the process of initiating new clinical trials in Australia significantly more efficient (Clinical Trials Action Group, 2011). Foremost was the introduction of a more efficient research review processes, supported by recommendations of standardising business items and the prices of hospital services to assist in expediting budget negotiations.

3.2.5 Characteristics of commercial clinical trials

A clinical trial is a form of human research designed to determine the effects of a medical intervention, including a treatment or diagnostic procedure (The National Health and Medical Research Council, the Australian Research Council and the

AustralianVice-Chancellors' Committee, & Commonwealth of Australia, 2007). Commercial clinical trials are uniquely positioned in healthcare. While they can offer innovative clinical treatment, clinical trials differ from standard patient care and other research. In particular, a commercially sponsored clinical trial intending to market an innovative pharmaceutical product or medical device differs from non-commercial trials because of its business focus.

> The pharmaceutical industry has a number of unusual characteristics, both in its structure and in the nature of its business operations, which are little known outside the industry but which materially affect the process of bringing new pharmaceuticals to the patient (Taylor, 2015, p.2).

There are five elements of clinical trials that relate to the pressures they exert for an optimal clinical trial environment. These are: the clinical trial "pipeline"; global business of clinical trials; clinical trial registration; commercial management decisions and the patent system. Separately and together these elements pressure healthcare agencies to meet the rigorous conditions required for commercial data collection, including those outlined in the Good Practice Guidelines (Therapeutic Goods Administration, 2000).

3.2.5.1 Clinical trial "pipeline". To bring a drug or device to market, a series of identifiable "pipeline" steps, through which the product efficacy can be evaluated, are required. Prior to undertaking human trials, pharmaceutical companies conduct extensive pre-clinical studies, including in vitro (test tube or cell culture) and in vivo (animal) experiments in which wide-ranging doses of the study drug are used to obtain preliminary efficacy, toxicity and pharmacokinetic information. These tests enable the company to determine whether a drug candidate has sufficient scientific merit to proceed for further development as a new investigational product. Routinely, trials then are expected to proceed through Phases I to III as indicated in Table 3.1. Each phase has a separate focus. Early phase trials focus on safety but Phase II and III concentrate on the efficacy of the experimental product. Post marketing or Phase IV studies are conducted to identify and evaluate any long-term effects of a marketed product over a lengthy period for a greater number of patients in a "real life "situation (Table 3.1).

Table 3.1 Clinical Trial Phases

Phase	Primary goal	Dose	Typical number of participants	Length of Study	Notes
Phase I	'First in human' studies. Testing of drug on healthy volunteers for safety and dosage	Often sub therapeutic, but with ascending doses	20-100	Several months	Approximately 70% of drugs move to the next phase
Phase II	Testing of drug on patients to assess efficacy and safety	Therapeutic dose (may have dose range)	Up to several hundred people with the disease or condition	Several months to 2 years	Approximately 33% of drugs move to the next phase
Phase III	Testing for efficacy and monitoring of adverse reactions	Therapeutic dose	300 to 3000 volunteers who have the disease or condition	1 to 4 years	Approximately 25-30% of drugs move to the next phase
Phase IV	Post marketing surveillance – watching drug use in public for safety and efficacy	Therapeutic dose	Several thousand volunteers who have the disease/condition	NA	Evaluate product for long-term effects

Adapted from The Drug Development Process by the Food and Drug Administration, Retrieved from https://www.fda.gov/forpatients/approvals/drugs/ Copyright 2015 by the U.S. Food and Drug Administration

Table 3.1 also shows the total percentage of trials at each stage. It has been estimated that more than 80% of all investigational drugs and devices that enter the pipeline are not marketed (Fisher, Cottingham, & Kalbaugh, 2015)[2]. Industry data estimates that drug development takes over a decade and costs over US$2 Billion ("Tufts New Estimate of Costs to Bring a Drug to Market & Beyond," 2016).

[2] Fisher et al.(2015) compared the pharmaceutical industry's investments in research and development (R&D) of drugs that target diseases in high-income and low-income countries. They found 3.46 times higher investment in drugs for diseases prevalent in high-income countries in than drugs for diseases prevalent in low-income countries, despite saturation of Western markets and limited innovation of new therapeutic benefit. The figures relating to attrition in drug development reflect high income R&D processes.

At the completion of each phase, clinical trial sponsors seeking regulatory approval from authorities such as the U.S. Food and Administration (FDA) and the European Medicines Agency (EMA) must submit detailed clinical study reports (CSRs) and individual participant data, which form the basis for continuing to the next phase or the marketing application for a product. In regulatory submission studies, accurate generation, gathering, and analysis of data as well as maintaining an audit trail of data management activities is of paramount importance in order to demonstrate that the investigated product acted as claimed.

Figure 3.2 depicts the outcome of each stage that proceed to the next stage as a percentage of the previous stage, in comparison to Table 3.1 that showed absolute figures. It suggests that over half of Phase II trials, which evaluate safety and efficacy as in a proof-of-concept, do not move to the next "pipeline" stage. Drugs that do not exhibit sufficient therapeutic promise or are not well tolerated are likely to be discontinued at this stage.

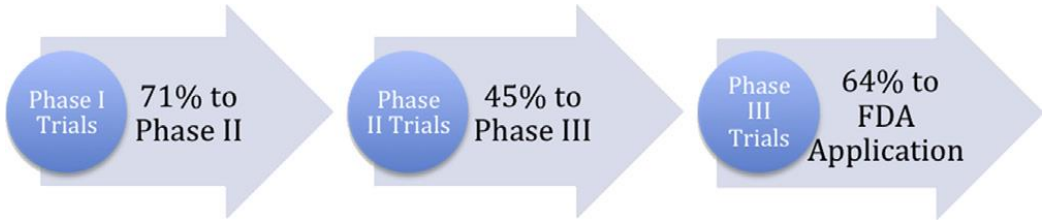


Figure 3.2: Visualisation of the pharmaceutical pipeline

Reprinted from Peering into the pharmaceutical "pipeline": investigational drugs, clinical trials, and industry priorities By J. A.Fisher, M. D Cottingham & C. A. Kalbaugh .2015. *Social Science & Medicine*, 131. p 273.

The possibility of discontinuation, and the consequent economic and business implications, compels clinical trial teams to determine any efficacy, safety, or feasibility issues early in the trial pipeline. Any deviations from the study protocol must be reported to the study sponsor in an expedited manner (Therapeutic Goods Administration, 2006).

Each phase of the pipeline is defined and managed through a study protocol, a template of how the trial is to be conducted, that describes the objective(s), design, methodology,

statistical considerations, and organisation of a trial. It may only be amended by the trial sponsor on approval from the overseeing ethics committee. The format and content of clinical trial protocols, especially those sponsored by pharmaceutical, biotechnology or medical device companies, are standardised in accordance with Good Clinical Practice (GCP) (Abraham, Grace, Parambi, & Pahuja, 2008).

Within multi-site clinical trials, standardisation allows data to be combined across all investigators and sites. It also allows clear identification and audit trails of all aspects of the research process. The clinical trial model provides a useful vehicle for collecting concurrent data, such as economic, resource use, outcome data (clinical responses) and pharmacovigilance (safety) information that can be itemised or traced to specific events (Hansson, 2014).

The pharmaceutical industry is based on large amounts of human health care data related to a specific intervention with the primary intent of commercial gain. This combination of factors introduces many governance challenges, ranging from routine management to consistent address of ethical principles. Global trends have combined to create an extensive industry that is undertaken in numerous countries but which increasingly emphasises the need for similar practices internationally.

3.2.5.2 Global business of clinical trials. Typically, the success or failure of a research project is determined in relation to the study findings. However, literature shows that the business side of research is also developing prominence, as indicated in the following.

> Slow start up times are frequently referenced by clinical trial sponsors, collaborative research groups and researchers as the single most important factor as to why Australia is no longer an attractive option for commercially sponsored international, multi-centre clinical trials (NSW Ministry of Health, 2013, p. 6).

Predictability of the operating environment including costs, time to obtain the necessary approvals, and time to recruit the required numbers of patients has been identified as an essential component of planning for a multi-site project (Department of Health, 2015).

Lack of timeliness of research review impacts commercial decision-making and endangers Australia's role as an international competitor (Clinical Trials Action Group, 2011; Khan et al., 2013; Medicines Australia, 2011; NSW Ministry of Health, 2013). Timeliness and duplication of effort has also been identified as critical to non-commercial applicants (Webster & Temple-Smith, 2013; White et al., 2016). In particular this literature highlights the lack of consistency between ethical reviews and the site specific requirements of different healthcare agencies.

Globally, clinical research, especially clinical trials, has entered an era of unprecedented growth as a result of breakthroughs in biomedical sciences. New techniques such as those involving human genomics combined with commercial demands for expediency, have resulted in increases in investigations that are simultaneously undertaken at many locations. Three major areas in which the business of clinical trials has impacted will now be examined: clinical trial registration, growth of the numbers of clinical trials and how economic advantages to participating in commercial research have pressured regulatory reforms.

3.2.5.3 Clinical trial registration. Concerns regarding the selective reporting of clinical trials to promote positive findings were distorting the body of evidence available for clinical decision-making led the International Committee of Medical Journal Editors (ICMJE) to announce in 2004 that it would require registration of clinical trials as a condition for publication (International Committee of Medical Journal Editors, 2004). The ICMJE aim was full transparency of the performance and reporting of clinical trials. Data from these registries shows globally the number of registered clinical trials have increased five-fold since 2004, and that more than 20,000 clinical trials are now newly registered every year (Viergever & Li, 2015) but that at the same time, multicentre research, especially commercial clinical trials are relocating from the traditional Western research markets (Sung et al., 2003) into areas such as Asia, which offers large target populations (Battelle, 2014; Clark, 2009).

3.2.5.4 Commercial management decisions. Growth in the numbers of international clinical trials, especially where companies lacked specialist regulatory expertise to operate in foreign countries, led to the development of Contract Research Organisations (CROs). CROs are competitive, specialist service organisations that provide research

and support services to pharmaceutical, biotechnological, and health companies. In Australia, they can also act as the local commercial sponsor for inclusion of a therapeutic good or medical device on the Australian Register of Therapeutic Goods, for an overseas entity who is are not registered as an Australian legal entity with Australian Securities and Investments Commission (ASIC). Only an Australian legal entity can provide an indemnity (such as the Medicines Australia Indemnity) and evidence that it is covered by relevant insurance arrangements for the conduct of the clinical trial in case of participant injury or other unfavourable events. If a commercial company does not have a legal Australian presence, then they employ a CRO to act as, and assume all of the responsibilities of, a local commercial sponsor.

Thus, commercial companies outsource to CROs for increased efficiency, cost savings and also because CROs are more adept at coordinating international clinical research (Mirowski, 2005). The predominant CRO focus remains based on acceleration of new product development (Whitworth, 2012). Literature suggests that the outcome driven client/vendor dynamic between the commercial sponsor and the CRO has strongly influenced the growth of commercialisation of the biopharmaceutical sector (Mirowski, 2005).

Such outsourcing has been tied with growth of "harmonised" regulatory reform to create similar research environments in different countries. Good Clinical Practice (GCP) is the international language to facilitate mutual acceptance of clinical data by the regulatory authorities of associated jurisdictions. It provides guidance on the ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects, in order to provide evidence that subjects are protected and that the clinical trial data are credible (Therapeutic Goods Administration, 2000). While GCP was initially developed to manage data generated by clinical trials intended to be submitted to regulatory authorities, the document also suggests application to "other clinical investigations that may have an impact on the safety and well-being of human subjects" (Therapeutic Goods Administration, 2000p. 6).

Global trends in corporate obligations of research sites undertaking multicentre research also promote clear allocation of roles and responsibilities. Institutions are expected to

promote the responsible conduct of research and establish an appropriate research governance framework for risk mitigation, including staff training (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007). Contractual agreements are routinely undertaken between all parties to establish role expectations and to establish the basis for litigation if required. The nature of these contracts depend less on the nature of the research being undertaken, than on the current expectations of what needs to be contracted.

3.2.5.5 The patent system. Patents are a critical factor in pharmaceutical development to allow recouping the cost and effort involved in developing new products. The purpose of a patent is to grant a limited monopoly on the use of a product that prevents others persons from exploiting the patented invention. For example, Australian patent rights are legally enforceable and provide the owner exclusive rights to commercially exploit the invention for a period of up to 20 years (Australian Government, Department of Industry Innovation and Science, & IP Australia, 2015). Australian patent law, the *Patents Act 1990 (Cth),* is administered by the Commonwealth Government agency IP Australia. Australian patent law is broadly comparable with patent law in other major countries. Australia is also a member state of the World Intellectual Property Organization (WIPO), and compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which introduced intellectual property law into the international trading system.

Currently, the term of a new patent is 20 years from the date on which the application for the patent was filed in Australia and can be issued or expire at any time regardless of the drug's approval status. Patents can be granted at any time during the development process but costs are recouped only after the product is marketed. Consequently, timeliness of all steps of the developmental phases is a critical feature of this industry.

Global trends in clinical trials depict a highly competitive global industry. While there are clinical and financial benefits to involvement, the sector is also characterised by regulatory compliance and commercial practices. An optimal research landscape is not something provided by a single organisation but requires investment at government level to ensure all organisation hold the same standards.

3.3 Research regulatory landscape

Due to the heterogeneity in the regulatory landscape of the various Australian states and territories, there is currently no single, national legislative and regulative framework to oversee clinical trials. The history and political dynamics of each jurisdiction have created individual legislative and regulatory frameworks.

3.3.1 Research reform

Over the past half century, pharmaceutical and device companies have embraced globalisation as a core component of their business models, especially in the realm of clinical trials (Glickman et al., 2009). Globalisation, however, has highlighted social and economic disparities. While proponents describe the economic and clinical benefits of participating in commercial clinical trials; there is potential for emerging markets in clinical trials to exploit the involvement of developing countries and also for divergent practices to negatively impact the characterisation of safety profiles of marketed products (Wathall , di Giovanna, & Smith 2014). These phenomena raise important scientific, ethical and business concerns that have initiated movements towards the harmonisation of international clinical research.

Globally, unprecedented growth of multi-site clinical trials over the past few years has led to extensive review of the existing regulatory systems around health and medical research. One driver for reform has been the potential clinical and economic benefits for those counties participating commercial clinical trials. In order to appeal to commercial interest, many countries have instigated the consolidation and reconsideration of their research regulatory sectors (Manville et al., 2013). Much of the impetus towards single ethical review has been driven by commercial pharmaceutical interests (Fitzgerald & Phillips, 2006; Manville et al., 2013; Viergever & Li, 2015). Multiple and duplicative bureaucratic processes in particular have raised concerns (Hirshon et al., 2002; Khan et al., 2013; Krastev, Grimm, & Metcalfe, 2011; Mallick & O'Callaghan, 2009; Medicines Australia, 2011; Petch, Doig , & Mike, 2013; Shaw, Petchey, Chapman, & Abbott, 2009; van Teijlingen, Douglas, & Torrance, 2008; Webster & Temple-Smith, 2013).

3.3.2 Research reform in Australia

Australia's research regulatory reform has been influenced by a variety of political, health, community and industry factors. Recommendations made to the Federal Government have noted the importance of multi-site clinical trials to the Australian economy and the need to rationalise research bureaucracy (Commonwealth of Australia, 1966, 1996). By mid-2000, recommendations on how reform should progress in Australia included reconstruction of the NHMRC (Saunders, 2000) and the establishment of national systems of streamlined ethical and scientific review of multi-site research proposals (Pittman, 2007). The NHMRC further revised its guidance to allow for single ethical review and separated site specific requirements (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007; The National Health and Medical Research Council et al., 2007).

Australian research reform towards single ethical review has been further driven by a series of evaluations and regulatory updates (Clinical Trials Action Group, 2011; McEwen, 2007; McKeon, 2013; Medicines Australia, 2011; Pittman, 2007). Several reports recommended changes to the configurations of how research was perceived and managed.

Australia has also been strongly influenced by research reform in the UK, which has formally divided ethics and site governance responsibilities (Health Research Authority (HRA), 2015). It is important to note, however, that under the *National Health and Medical Research Council Act 1992 (Cth) (AustlII),* neither the National Health and Medical Research Council *(*NHMRC) nor its advisor, the Australian Health Ethics Committee (AHEC) has the authority to force the uptake of mutual acceptance or centralised model of ethics review as in the UK model (Breen, 2005b). Breen, who was the AHEC Chair in 2005, made a further observation that the active participation of Federal, State and Territory governments was required to create a national system of ethical and scientific review of multi-site clinical trials (2005b).

3.3.3 Inter-jurisdictional research

A central tenet of clinical trial reform in Australia is based on the need to appear as one research destination to commercial investors. Strategic priorities from government have

been to rationalise research bureaucracy and harmonise research processes between research entities.

A key element of reform around clinical trials has been to address inter-jurisdictional differences through the connection of committees and working groups. The peak intergovernmental forum in Australia is the Council of Australian Governments (COAG) and its advisory body, the Australian Health Ministers' Advisory Council (AHMAC), which provide a mechanism for the Australian Government and state and territory governments to discuss matters of mutual interest concerning research policy. Figure 3.3 presents a diagram of the key governing bodies in the Australian research sector and their roles and relationships.

AHMAC has six principal committees, which manage the business of AHMAC and provide advice, one of which is the Hospitals Principal Committee (HPC). The role of the HPC is to advise AHMAC on activities which largely relate to hospitals including implementation of the health reform agenda as it applies to hospital care. Two advisory committees feed into the HPC: the Clinical Trials– Jurisdictional Working Group (CT-JWG) and National Mutual Acceptance Advisory Group.

The CT-JWG was established in 2014 to enable the environment multi-jurisdictional clinical trials in Australia and improve international competitiveness. CT-JWG membership includes senior officials from Commonwealth and state and territory health departments, and the NHMRC. A second advisory group is the National Mutual Acceptance Advisory Group, largely comprised of State and Territory health officials, which advises specifically on the advancement of the NMA.

Another committee, the Clinical Trials Advisory Committee (CTAC) does not report to COAG but to the Minister of Health and the Minister of Industry and Science on various measures under the clinical trials reform initiative. Many of these activities progress implementation on recommendations from the Clinical Trials Action Group Report "*Clinically competitive: boosting the business of clinical trials in Australia"* (2011).

The intersection of these groups, and the framework in which they are positioned, are outlined in Figure 3.3. The figure shows reporting lines to State and Federal Health Ministers as well as the Minister for Industry and Science so that the three government stakeholders are informed.

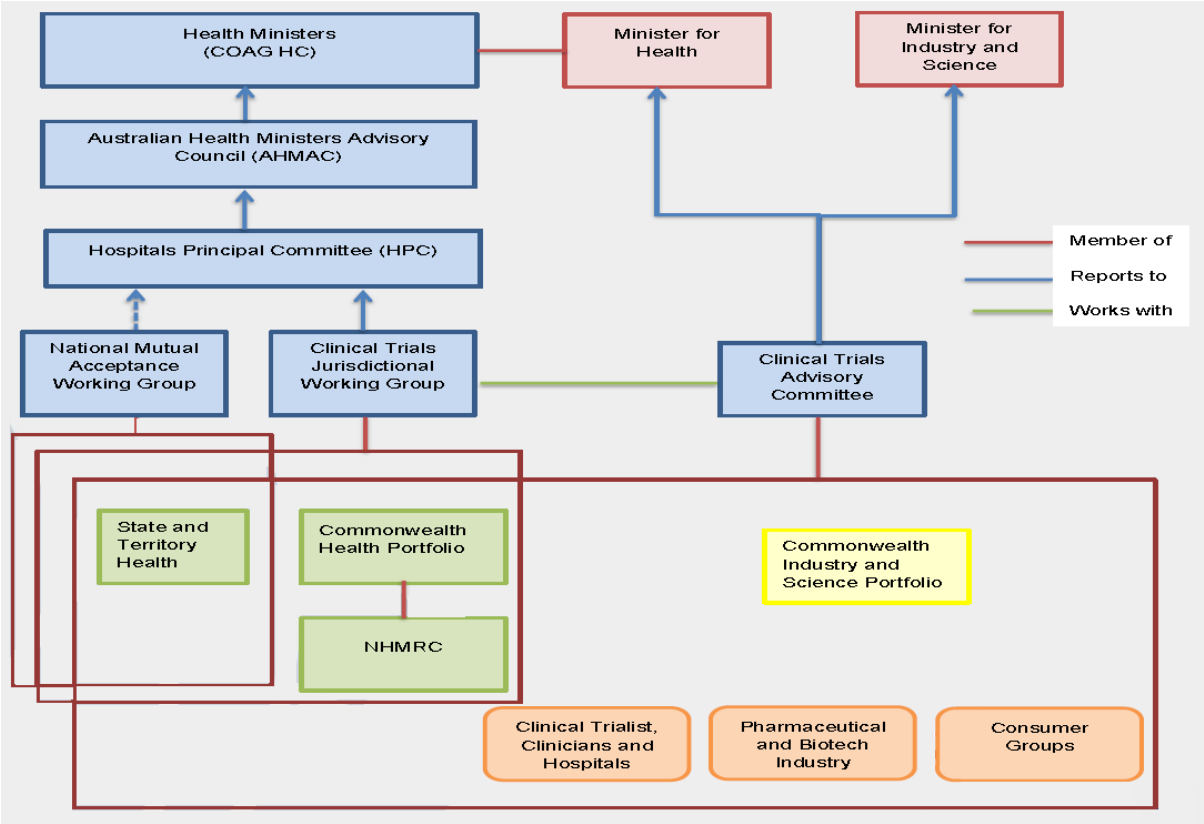


Figure 3.3: Key governing bodies in the Australian research sector

Reprinted from *Clinical Trials – Jurisdictional Working Group: Update* by J. Cokayne. 2015. Paper presented at the ACTA 2015 International Clinical Trials Symposium, Sydney, Australia.

3.3.4 Regulation and compliance

Australian clinical trials are regulated at a number of levels under both Commonwealth and state and territory legislation. There are many laws, regulations, formal and informal guidance documents, and other standards that govern research activities. Within Australia, the standard governance framework for agencies performing clinical research and trials involving humans includes:

- At a Commonwealth level, the Therapeutic Goods Administration (TGA), a division of the Commonwealth Department of Health, regulates medicines and medical devices (Therapeutic Goods Administration, 2000, 2004, 2006, 2015).
- Guidance from the NHMRC, including: the *Australian Code for the Responsible Conduct of Research* (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007); the *National Statement on Ethical Conduct in Human Research* (The National Health and Medical Research Council et al., 2007); and other guidance specifically aimed at particular research topics, such as genetic studies (National Health and Medical Research Council, 2015)
- Relevant Commonwealth, State and Territory legislation (National Health and Medical Research Council, 2014c)
- The agency's own regulation and policies; and
- Contracts and agreements (for example notification to the TGA, funding agreements, clinical trial research agreements, research collaboration agreements and indemnity) (Department of Health & Human Services, 2015).

Expectations regarding clinical trials are developed by government bodies or agencies at federal or state level and national or international institutions. The principles applied by each authority serve as a basis for assuring the integrity of clinical trials and ideally provide a formal basis for mutual recognition of clinical data generated within other countries.

Effective regulation of medicines requires a variety of additional functions, such as: evaluation of safety and efficacy data from clinical trials; licensing and inspecting manufacturing facilities and distribution channels; monitoring adverse drug reactions for investigational and marketed drugs; and controlling drug promotion and advertising. Regulatory bodies that oversee these functions are usually founded in law. In its most straight-forward sense, regulation refers to a set of authoritative rules accompanied by a mechanism, usually administered by a public agency, for monitoring and promoting compliance with those rules (Johnstone & Sarre, 2004). In recent decades, a growing recognition of the multi-faceted nature of compliance to regulation has seen increasing reliance on interconnectivity between regulatory bodies to ensure that common aims are met.

Medicines regulatory bodies, such as: USA Food and Drug Administration (FDA); European Medicines Agency (EMA); and the Australian Therapeutic Goods Administration (TGA) provide oversight of the therapeutic drug and device manufacturing and distribution supply chains which are increasingly elaborate and globally integrated. Approval from a medicines regulatory authority is required for any access to a therapeutic or experimental product in that country (Therapeutic Goods Administration, 2017). The activity of these bodies is enabled and constrained by various factors including the laws, socio-political cultures and the procedures used in each country.

For example, the Australian *Therapeutic Goods Act* 1989 (Cth) (AustlII*)* sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia to ensure that the TGA is able to ensure that medicines, medical devices, blood and blood products meet the expected safety levels. Part of this assurance is that only Australian legal entities may conduct a clinical trial.

To apply for permission from the TGA to undertake a clinical trial involving unapproved therapeutic goods in Australia, an applicant must submit a Clinical Trial Notification (CTN) or the Clinical Trial Exemption (CTX) (Therapeutic Goods Administration, 2004). Only an Australian entity may complete the sponsor section of the TGA forms. Requirement for the trial sponsor to be an Australian entity is reinforced by conditions imposed by the standard indemnity provided by Medicines Australia. Medicines Australia represents and promotes the pharmaceutical industry in Australia by liaising with government and other groups to develop health and industry policy. In this situation, an indemnity involves an agreement, between a pharmaceutical company sponsoring a clinical study and the institution that hosts the study, to cover any loss and damage suffered as a result of participation in the trial. The state's insurer, Victorian Managed Insurance Authority (VMIA) endorses the Medicines Australia forms.

International, commercial, multi-site clinical trials also need to reflect the regulatory framework of the country in which they intend to register their investigative product. Trials intended to be registered in the USA must comply with the USA legislation *The Federal Food, Drug, and Cosmetic Act* 1938(USA), which is the basic food and drug

law of the U.S, and the USA *Code of Federal Regulations* (*CFR*) which is the codification of the general and permanent rules and regulations. Clinical trials intended to be registered in the European Economic Area (EEA) have to comply with, or be equivalent to, the European Union (EU) clinical-trial legislation (Directive 2001/20/E).

Differences in regulatory frameworks have led to a number of harmonising strategies: most notably to maintain the quality of international trials through Good Clinical Practice (GCP) guidelines and the International Coalition of Medicines Regulatory Authorities (ICMRA).

3.3.5 Management of ethical integrity

The ethical and scientific standards for biomedical research on human subjects have been developed and established in international guidelines, specifically the *Nuremberg Code, Declaration of Helsinki* and *the Belmont Report* (Gordon & Prentice 2000) as well as on the outcome of a series of unethical studies famously listed in a publication by Dr Henry Beecher (Beecher, 1966). These guidelines helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible.

There are numerous examples of where ethical considerations of the protection of human subjects in biomedical research are required, including research that involves: innovative drugs and devices; clinical trial registries; privacy/data protection; human biological materials; and studies involving genetic data, embryos, stem cells or cloning as well as where the competency of the subject's consent is questioned. Many of these categories of ethics considerations have also been legislated, so that there are legislated penalties for non-compliance. For example, in Victoria, recruitment of patients unable to consent to taking part in medical research for themselves are required to meet Victorian legislative requirements, that is, the *Guardianship and Administration Act* 1986 (Vic) (AustlII), in conjunction to an HREC approval (Victorian Department of Health and Human Services, 2016a). Penalties apply for non-compliance.

By the last decades of the previous century, most countries developed their own regulations or guidelines for the protection of human research participants based on the general guidelines (Office for Human Research Protections, 2016).

Globally, ethics committees have played a central role in the review and oversight of human research since their establishment in the USA the late 1960's (Schneider, 2014). At the time of ethics committee introduction, there was very little legal or regulatory framework surrounding research, so the responsibility for determining research merit fell on the organisation undertaking the research. Organisationally based HRECs became the primary authority of whether or not a research project could be undertaken.

World-wide in countries performing research, approval from an ethics committee is required prior to commencement of a research project and remains a central tenet in the protection of human subjects. Ethics committees were created to ensure the ethical integrity of a research project and the ethical review provides provide a common element of integrity across different countries. Globally, ethics committees have various titles. In the USA, the title is Institutional Review Board (IRB), in the UK Research Ethics Committee (REC) and in Australia the title is Human Research Ethics Committee (HREC). The term HREC is generally used in this thesis. Historically, HRECs were associated with an institutional basis and a mechanism of enforcement which tied compliance to decisions from the ethics committee to research funding.

In Australia, beginning with the passage of the *Medical Research Endowment Fund Act 1937(*Cth.) (AustlII.), responsibilities for the government research funding was tied to the advice of the National Health and Medical Research Council (NHMRC), constituted in 1936. The current *National Health and Medical Research Council Act 1992 (*Cth.) (AustlII.) further reinforces this position (The National Health and Medical Research Council et al., 2007).

In 1985 review by an appropriately constituted ethics committees, became 'mandatory'. The NHMRC determined that

> Release of NHMRC research funds was to be conditional on

> (a) the research proposal being prospectively reviewed by an ethics committee and (b) that all other proposals for research involving humans in that institution were similarly subject to such prospective review (Breen, 2005b, p.9).

Prior to the commencement of the new state based arrangements for single ethical review in in 2007, the organisations had developed and maintained individual arrangements. Some of those bodies had been operating in this manner for over 50 years and institutional ethics review had become a static, familiar and local presence. They had also become a "catch-all" for all research issues, so that research contracts and advice to regulatory bodies also came within the province of the HREC. Breen further explains how organisational concerns about the legal exposure in clinical trial review and of the increased independence of institutions, strengthened organisational autonomy in clinical trial review, left HRECs deeply resistant to devolving or sharing any of their responsibilities for ethical review (Breen, 2005a, 2005b).

As the numbers of multi-site clinical trials and other research increased, the frustrations of researchers facing submission to multiple organisational HRECs became clear in the mid-1990s. Pressure mounted for action to simplify multi-site applications (Commonwealth of Australia, 1996) but this was balanced by objections from institutions faced with losing control of the review process (Breen, 2005b).

In 2007, issue of the updated *National Statement on Ethical Conduct in Human Research* (The National Health and Medical Research Council et al., 2007) and the new *Australian Code for the Responsible Conduct of Research* (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007) allowed the separation of ethical review from what was seen as the specific responsibilities of the research site. The creation of single ethical review is not mandated in law, but created through memorandums of understanding between the state government and healthcare agencies.

However, guidance for the responsibilities for the management of research integrity, including ethical integrity, suggests that it still remains within organisational province. For example, advice regarding public health sector insurance policies requires that

notification of serious issue pertaining to clinical trials is made to the insurer as well as the relevant HREC (Victorian Managed Insurance Authority, 2015). This suggests the likelihood of a cultural clash between the national goals of the NMA and the organisational risk management practices, as identified in previous literature (Franck et al., 2004).

3.3.6 Protection of the participating organisation

In Australia, public healthcare organisations regularly undergo an accreditation process through an independent, external peer assessment of that organisation's level of performance in relation to the National Safety and Quality Health Service (NSQHS) Standards. The NSQHS Standards were developed by the Australian Commission on Safety and Quality in Health Care to provide a nationally consistent statement about the level of care consumers can expect from health services.

> Clinical Care Standards can play an important role in delivering appropriate care and reducing unwarranted variation, as they identify and define the care people should expect to be offered or receive, regardless of where they are treated in Australia (Australian Commission on Safety and Quality in Health Care, 2015).

The experimental focus of interventional research and clinical trials depart from standard clinical care and present both opportunity and risk to the organisation undertaking the research. Opportunities involve access to innovative treatment, as previously discussed, but the same access can expose an organisation to legal liability if a research participant is harmed through trial participation. Healthcare agencies are required by their jurisdictional insurer to ensure protection from unforeseen events through effective indemnity and insurance arrangements.

There are two separate, but related, aspects to indemnity and insurance arrangements for clinical trials undertaken by public healthcare agencies (Rallis Legal, 2014). The first concerns the indemnity and insurance arrangements taken out by the healthcare agency that conducts or participates in clinical trials to protect that entity against liabilities that may arise in relation to their involvement. The second concerns the indemnity and

insurance requirements provided by a commercial trial sponsor for the healthcare agency participating in a specific clinical trial.

In the public sector, each State and Territory jurisdiction provides indemnity or insurance coverage to its respective public health services. The arrangements are implemented and managed through a State or Territory insurance agency. In Victoria, the Victorian Managed Insurance Authority (VMIA) provides public and products liability insurance to cover public healthcare agencies for legal liabilities arising from their business activities that result in personal injury or property damage to third parties. This insurance covers the organisation, its employees, volunteers, board members and people that represent the business (Victorian Managed Insurance Authority, 2015). Clinical trials coverage is a subset of the VMIA coverage.

Commercially sponsored clinical trials differ from other research because they are focussed on marketing an innovative drug or medical device, or new use for a marketed product. Figure 3.4 provides an overview of the basic arrangements involved in a commercial clinical trial. The clinical trial is initiated by a commercial sponsor (the sponsor) and the relationship between the sponsor and the organisation is governed through a comprehensive contract. A Clinical Trial Agreement (CTA) or Clinical Trials Research Agreement (CTRA) is used to describe the relationship between the sponsor and agency for drug or biological trials and a Clinical Investigation Research Agreement (CIRA) is used when a medical device company sponsors a clinical trial. If the company does not have a legal presence in Australia, a contract research organisation (CRO) is engaged to conduct and administer the study on its behalf. In that case, the CRO acts for the sponsor as is a signatory to the contract.

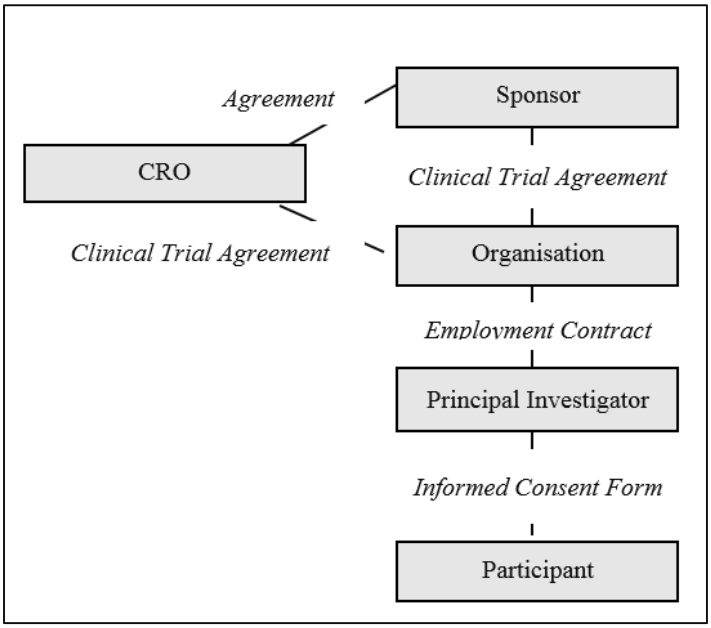


Figure 3.4 : Standard Australian arrangements for the conduct of clinical trials

Adapted from The *London experience. The TGN 1412 Trial* by A.Rallis. 2007. p. 1.

A comparison of the contracts and issues related to commercial and non-commercial trials is provided in Table 3.2. While the VMIA's public and products liability insurance covers public healthcare agencies for legal liabilities arising from their involvement with research, additional coverage is required for participation in commercial trials. Commercial sponsors also provide a separate Medicines Australia indemnity accompanied by a current insurance assurance to the healthcare agency. Through these arrangement, the commercial sponsor agrees to provide compensation in accordance with *Medicines Australia Guidelines for Compensation for Injury Resulting in Participation in a Company-Sponsored Clinical Trial* (Office for Health and Medical Research, 2015).

Table 3.2: Comparison between the documents of a commercial trial compared to non-commercial

Issue	**Sponsor-Initiated Study or when CRO acts as a local sponsor**	**Investigator-Initiated Study (IIS)**	**Collaborative or Cooperative Research Group (CRG)**
Protocol Author	Commercial sponsor	Investigator	CRG
CTN/CTX sponsor	Commercial sponsor	Healthcare agency/Investigator	Healthcare agency/CRG/ Investigator

Indemnification[3]	Standard Indemnity Form Standard Indemnity Form for a Clinical Investigation on Medical Technology (Non-MA)	Not required	Not required
Clinical Trial Research Agreement (CTRA) **Supported by Medicines Australia (MA)**	Medicines Australia Standard Form Contract Research Organisation acting as the Local Sponsor Collaborative or Cooperative Research Group (CRG) Studies Phase 4 Clinical Trial (Medicines) Phase 4 Clinical Trial (Medicines) Contract Research Organisation acting as the Local Sponsor CIRA Commercially Sponsored Trial of a Device (non-MA)	Investigator initiated (non-MA)[4]	Collaborative or Cooperative Research Group (CRG) Studies [5]
Data	The sponsor owns study materials and research results Agency owns medical records and other source data	Investigator (or agency) owns study materials and research results Agency owns medical records and other source data	CRG owns study materials and research results Agency owns medical records and other source data
Intellectual property (IP)	The sponsor owns patentable inventions conceived and reduced to practice.	Investigator (or agency) owns all inventions and IP	CRG may claim all inventions and IP
Funding	Commercial sponsor	Competitive and non-competitive grants, institution	Competitive and non-competitive grants, institution

[3] Victorian insurance or indemnity arrangements provide coverage to their insured or indemnified entities in relation to all types of clinical trials. If a claim is made against the healthcare agency, it would be expected that the agency would first turn to its insurer (VMIA). The agency or insurer may then may then pursue a commercial sponsor (or any other party) which has caused or contributed to the claim (Rallis Legal, 2014)

[4] Both the CRG and IIS standard agreements have the same general liability and insurance clause. The intent of the clause is that each party is liable for its acts and omissions in relation to the conduct of the study (Victorian Managed Insurance Authority, 2015, p.4)

[5] Ibid p. 4

Formal arrangement are also made with the TGA through either a Clinical Trial Notification (CTN) or a Clinical Trial Exemption (CTX) (Therapeutic Goods Administration, 2015). Table 3.2 also notes the ownership of data and intellectual property (IP) generated from the study. In a commercial project, these agreements establish the sponsor as the owner and findings from commercially sponsored trials are regarded as commercial in confidence, which, if disclosed, may result in damage to a party's commercial interests, intellectual property or trade secrets.

3.4 International harmonisation and GCP

Concerns regarding the spread of international commercial clinical trials and varying regulatory practices began emerging late last century and fuelled a movement toward globally applicable standards for the conduct of research on human subjects. This has led to the creation of a number of international regulatory initiatives and agencies focussed on how regulatory frameworks address international best practice (Therapeutic Goods Administration, 2016). Good Clinical Practice (GCP) is of particular importance in the context of this discussion because of its contribution to documenting specific tasks of best practice in conducting a clinical trial.

3.4.1 Good clinical practice

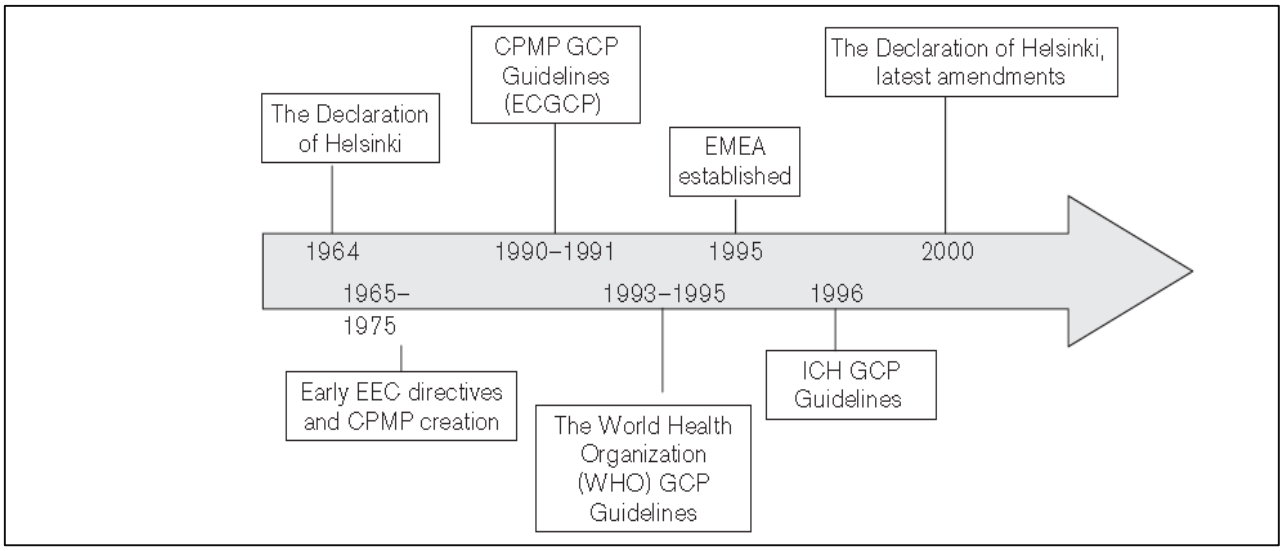
By the 1990's, the diverse regulatory requirements of different countries led to calls for international harmonisation or synchronisation of research standards. This led to the issue of the *Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance* (U.S. Department of Health and Human Services, 1996). Good clinical practice (GCP or ICH-GCP) is an international quality standard for clinical trials involving pharmaceutical products and the lesser known International Organization for Standardization (ISO) 14155 (ISO-GCP) is the international standard for medical devices (Vijayananthan & Nawawi, 2008).

These guidelines aim to provide globally accepted guidelines and standards for the conduct of clinical trials to:

- protect the rights, safety and welfare of human subjects
- improve the quality of data
- create more timely procedures, and

- speed the marketing process, and decrease the cost to sponsors.

Compliance with these standards is also intended to provide assurance to the public that the data collection is consistent with the principles of the *Declaration of Helsinki* and that the study findings are credible (U.S. Department of Health and Human Services, 1996).



CPMP, Committee for Proprietary Medicinal Products; ECGCP, a commonly used abbreviation for a document, published by the CPMP, titled Good Clinical Practices for Trials on Medicinal Products in the European Community; EMEA, European Medicines Evaluation Agency; EEC, European Economic Community; ICH, International Conference on Harmonisation

Figure 3.5: Milestones in the development of Good Clinical Practice (GCP).

Reprinted from Good clinical practice: Historical background and key aspects by A.Otte, H. M Lenzb, & R. A. Dierckxc, 2005, *Nuclear Medicine Communications*, *25*, (p 567

Figure 3.4 provides an outline of the development of GCP, denoting the contribution of both regulatory and commercial influences. In the 1960's concerns from the European Economic Community (EEC) paired with the Committee for Proprietary Medicinal Products (CPMP) to articulate commercial concerns regarding the regulatory variations between countries. The CPMP goals were in accordance with the *Declaration of Helsinki*, which was drafted in response to the revelations of Nazi atrocities of the Nuremberg trials conducted after World War II (Fischer, 2005). Drafters of GCP sought to ensure that human subjects involved in clinical research would have their rights, safety and well-being placed above all other considerations in clinical research (National Health and Medical Research Council, 2014a).

In 1991, the CPMP publication entitled *Good Clinical Practices for Trials on Medicinal Products in the European Community* (also known as EC GCP), became effective. GCP development was further supported by the World Health Organisation (WHO), and creation of the European Medicines Evaluation Agency (EMEA) so that by 1996 the International Conference on Harmonisation (ICH) was able to issue the *ICH Guidelines: Topic E6 Guideline for GCP*, which is still current (Otte, Lenzb, & Dierckxc, 2005).

GCP was developed, and is maintained, through both research regulatory bodies and industry representation, to become a ubiquitous presence in the guidance for undertaking clinical trials. In Australia, for example, the *National Statement on Ethical Conduct in Human Research* (National Statement) (The National Health and Medical Research Council et al., 2007) states that research must meet the relevant requirements of the Australian TGA adaption of ICH-GCP, the *CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices*, and relevant TGA requirements. The National Statement also states that institutions must be satisfied that sponsors of trials have made the required indemnity or insurance and compensation arrangements in keeping with this advice.

Use of an ethics committee is also a requirement of GCP. GCP specifies the documents to be initially reviewed and listed on the ethics committee's approval letter, the terms in which the committee's decisions should be couched and that the committee should require progress advice, at least annually (U.S. Department of Health and Human Services, 1996). GCP does not change the responsibilities of the ethics committee in safeguarding the rights, safety, and well-being of all trial subjects, but it does standardise the appearance of those responsibilities and allow them to be quantified. For example, GCP states the items for which written and dated ethics approval is required.

> Before initiating a trial, the investigator/institution should have written and dated approval/favourable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects (Therapeutic Goods Administration, 2000, p. 16).

Ongoing globalisation has been dominated by regulatory agencies and multinational firms which require standard rules for innovative product registration and issues of risk-management and post-marketing safety (Otte et al., 2005). GCP describes how research participant welfare is to be addressed in clinical trials but it also addressed the kinds of expertise and information used to make risk-management decisions about pharmacovigilance (Demortain, 2015). GCP was partially revised in 2016 to adopt a more risk-based approach. The revision allows more efficient working methods in study management (such as, remote monitoring and oversight) and data management (such as, electronic data capture) (International Council For Harmonisation Of Technical Requirements For Pharmaceuticals For Human Use (ICH), 2016).

3.4.2 Timeliness and the regulatory environment

Timeliness and the accuracy of prediction are extremely relevant for any business endeavour because they underpin the ability of the business to create strategies and predict their outcomes. Timeliness has been identified as at the core of multi-site clinical trial review; emphasising that review processes should be completed within certain targets (Campion & Engwall, 2013; Manville et al., 2013; NSW Ministry of Health, 2013). This allows for predictability and the logistical planning of other processes such as management of human and other resources and delivery of the trial products.

The need for streamlined practices in research bureaucratic timelines was first addressed at the start of the century by the *European Union Clinical Trials Directive 2001/20/EC* (The European Parliament and the Council of The European Union, 2001). The Directive established a benchmark for ethics committee decisions to be made and confirmed to the applicant or Coordinating Principal Investigator (CPI) within 60 days from the date of receipt of a valid application. The Directive 2001/20/EC provided the minimum requirements for clinical trials to be incorporated into national law of each of the countries within Europe by May 2004. It was transposed into UK law through the *Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)*. In order to simplify and harmonise UK regulatory processes, single ethical review was introduced and the ethical review was separated from site specific processes. A decade later, the UK made further amendments which created the Health Research Authority

(HRA) to further standardise practices relating to regulation and establish Research Ethics Committees (RECs) independent from research institutions (Department for Business Innovation and Skills, 2011). [6].

The Australian National Mutual Acceptance (NMA) is similar to the UK system, in that they both involve separation of the ethics review from the site specific review, apply the 60 day benchmark and use a similar dedicated IT system to manage the application processes. However, whereas the UK system is fully centralised and compulsorily, the NMA relies on organisational HRECs. NMA performance metrics from October 2013 to 1 July 2015 indicate that, while over 75% of HREC approvals were within the 60 day benchmark, the majority of the Site Specific Assessments(SSA's), undertaken to determine the organisation's capacity to perform the research, fell outside 60 days and that diversity of SSA authorisation times continued (Hasthorpe, 2015).

3.5 Towards single ethical review

One of the main drivers in effective multi-site research is the need for consistency between sites; between the anticipated study milestones and the actual progress; and between the bureaucratic processes around research review. Thus, while ethics committees continue to play a central role in the ethical review and oversight of multi-site research, concerns were raised about delays caused by duplication and inconsistencies of multiple ethics committees reviewing the same project (Manville et al., 2013).

Consequently, single review was first introduced in the European Union through the *Clinical Trials Directive 2001/20/EC* (Veerus, Lexchin, & Hemminki, 2014) in order to streamline approval and contain costs. Since then, the majority of countries involved with multi-site clinical research have "streamlined" their ethical review processes to allow a single ethical review to be accepted at multiple sites (Manville et al., 2013).

[6] It is not yet clear how the UK will fare in the context of Britain's recent decision to leave the EU in June 2016. One view is that the EU control was too restrictive and without it Britain will attract more research, but another review is that the single application pathway to be offered through the EU will not include Britain so it will attract less trials and research.

3.5.1 Principles of single ethical review

Single or streamlined ethics review allows one human research ethics committee to review a multi-site research project on behalf of many sites. At the same time, each accepting site (those which accept the decision of the ethics committee) undertakes their own review of site specific requirements. Final permission for the project to commence may only be granted approval from the ethics committee and from the organisation intending to undertake the research has been granted. The Australian National Health and Medical Research Council (NHMRC) has proposed the following principles of single ethical review:

- *Efficiency:* agreed timeframes for processes and procedures are adopted in all jurisdictional systems.
- *Trust*: the single ethics review of a multi-centre research proposal is accepted by institutions without re-review by their institutional HREC.
- *Respect*: the National Approach accommodates the differences in jurisdictional statutory and administrative frameworks and institutional arrangements.
- *Compliance*: single ethics review of multi-centre human research meets the requirements of the National Statement to protect human research participants as well as meeting relevant jurisdictional statutory and administrative frameworks (National Health and Medical Research Council, 2016c).

The models through which single ethical review is implemented, however, can differ.

3.5.2 Different models of ethical review of multi-site research

Literature has identified different ways in which an ethics committee might approach review of multi-site research. Four possible approaches have been presented in Table 3.3.

Table 3.3: Four models for the ethical review of multi-site research

Model	Type	Explanation	Advantages and disadvantages
Model A	**Devolved review**	Institutions that conduct research establish an HREC and all research for which this institution is responsible is reviewed by that HREC (the status quo)	Advantages : Institution specific
			Disadvantages: leads to inconsistency because of the variety between different institutions,
Model B	**Mutual acceptance**	HREC to HREC. The HREC of an institution which conducts research agrees to accept the review of an HREC at another institution.	Advantages: Model uses existing HREC resources
			Disadvantages: May require further organisational endorsement of external HREC review
Model C	**Mutual acceptance: HREC to institution**	The research institution agrees to accept the review of another institution's HREC, instead of its own HREC, as one aspect of the decision to allow research to be conducted	Advantages: can be structured at a state or national level, to require common practices at all institutions
			Disadvantages: local preferences may override system requirements - can be time consuming for applicants
Model D	**Centralised review**	The research institution agrees to accept the review of a central HREC instead of its own HREC, as one aspect of the decision to allow research to be conducted.	Advantage : all reviews are standardised and do not have institutional bias
			Disadvantages: more expensive to establish

Adapted from Notes on session 3: developing solutions from the *Inter-jurisdictional Forum. Towards timely, efficient and effective review of multi-centre clinical trials* held by National Health and Medical Research Council. 2005. Sydney, p.41

Model A, the devolved model, depicts an organisational specific approach. In many ways, this is most risk averse because the organisation is responsible for all the decisions around the acceptability of the project. Alternatively, it is problematic for multi-site research because of the potential for the variety between different organisational reviews.

Model B is based on agreement between HRECs, so that the HREC of an institution, which intends to conduct a research project, agrees to accept the review of an ethics committee at another institution. While this provides more consistency than the devolved model, there is potential for the external HREC review to be rejected by those site personnel authorising the project.

Model C is based on organisational commitment to accept the decision of an HREC from another organisation. The NMA is based on Model C. While the reviewing HREC remains the responsibility of the organisation, and subject to organisational requirements, the CEO of the accepting organisation agrees to accept the external review. This is an effective approach in the public sector because government agreements can instigate common practices in the public sector. However, while there is more structure than the first models, there is capacity for local preferences to override the goals of the NMA.

Model D, centralised review, has been identified as the optimal mechanism to provide single ethical review across multiple organisations (McKeon, 2013). Centralised review involves the use of ethics committees that are independent of organisations undertaking research and are bound by the same operating procedures. The centralised model is used by Bellberry Ltd., a national, private not-for-profit Australian company which reviews research undertaken in the private sector (Bellberry Limited, 2017) as well as providing the basis of the New Zealand human research ethics system (Health Research Council of New Zealand, 2017). In the UK, the centralised research review system includes pathways for both ethical and governance review (Health Research Authority, 2016).

The centralised model of research review, currently employed in the UK, was created as part of a strategy to attract commercial research to the UK. It a highly regulated model in which legislation and government support provide key components. The formation of a single body overseeing research regulation and governance provides a single point of access and contact for researchers throughout the approvals process (Academy of Medical Sciences; Cancer Research UK; and The Wellcome Trust, 2012).

3.6 Australia's approach to a national model of single ethical review of multi-site research

The environment in which public healthcare research is undertaken is affected by the nature of the sector as well as the broader socio-political environment. The public sector supports the Government of the day in serving the community. It does this by implementing the decisions of the Government, which are, in turn, influenced by a combination of economic and political factors.

3.6.1 Two models of single ethical review

Australia has approached single ethical review through two differing paradigms. One developed by the National Health and Medical Research Council , *National Approach to Single Ethical Review of Multi-Centre Research* or *National Approach* (previously HoMER) (2016b) is intended for all multi-site research. The second, a State/Territory government initiative, the *National Mutual Acceptance* or *NMA,* was initially designed for clinical trials in the public health sector. Table 3.4 compares the two models. One significant difference relates to the standardisation of processes. Whereas the National Approach falls largely silent on how the flow of interaction between researchers and the review bodies is managed, the NMA requires that all applications are made through a dedicated IT platform.

The disparities between the two models suggest that Australia's journey towards a streamlined system is incomplete and the solution most probably lies in an amalgamation of the two approaches. There are limitations in restricting the NMA to the public sector and the level of control exercised by the government over public health institutions cannot be assumed for other sectors, but the use of a dedicated IT system allows collection of performance measures. Alternatively, the NHMRC National Approach enables any certified HREC to review any research but does not require adherence to a centralised IT system which, in turn, creates difficulty in collecting consistent performance measures.

Table 3.4: Comparison of the NHMRC National Approach and National Mutual Acceptance (NMA)

	NHMRC National model	**National Mutual Acceptance (NMA)**
Authority	Commonwealth Government via NHMRC	Commonwealth via States and Territories
Aim	National model, single HREC review	National model, single HREC review
Research type	All research	Commenced with clinical trials (2013), then opened to all research (2015)
Scope	All sector, including private health and universities	Aimed at public health sector, others may accept HREC decision
IT platform	Not specified	Specified dedicated IT system
Application forms	NHMRC form	NHMRC form for HREC review, SSA for site review and Victorian Specific Module (VSM) from dedicated IT system and DHHS website
Guidance	Guided by NHMRC	Guided by NHMRC but specific mention of GCP and relevant legislation
Legal / contractual	Not specified	Specific contract templates
HREC Certification	National Certification Scheme	National Certification Scheme and State /Territory government input
Standard forms/ templates	NHMRC Standardised participant information and consent forms (PICF), HREC template letters	NHMRC Standardised participant information and consent forms (PICF)

Currently, there are indications of merging: the NHMRC is involved in a number of targeted and public consultations that include management of clinical trials governance (National Health and Medical Research Council, 2014b) and the NMA now incorporates all research types, including health and medical research and that designated low risk (Department of Health and Human Services, 2016). However, despite this, the Australian research landscape continues to present challenges to a single ethical review approach.

3.6.2 Processes of the National Mutual Acceptance (NMA)

3.6.3.1 Background. The NMA is a national system for the mutual acceptance of scientific and ethical review for multi-site clinical trials conducted in publicly funded health services (Victorian Department of Health, 2013a). Participating governments are responsible for implementing the system within their jurisdiction and for providing ongoing oversight.

The NMA introduction is a phased approach, currently involving five jurisdictions: Queensland (QLD), New South Wales (NSW), Australian Capital Territory (ACT), Victoria (Vic) and South Australia (SA). At the time that this study was undertaken, Western Australia, Tasmania and the Northern Territory had agreed in principle.

Under the NMA, HREC reviews may be undertaken a limited number of accredited HRECs which remain attached to their healthcare agency. Mutual acceptance means the review of any HREC accredited to undertake an ethical assessment on behalf of the NMA is recognised by agencies from any state or territory participating in the scheme. In Victoria participating healthcare agencies are signatories to a Memorandum of Understanding (MOU) with the Department of Health and Human Services.

The NMA is intended to produce timely approvals of multi-site research increase Australia's chances of hosting international, commercial clinical trials (Department of Industry Innovation and Science, 2016). There are two aspects to the NMA: a mechanism able to promote consistent bureaucratic processes and the ability to provide metrics or standards of measurement that would allow comparisons between sites and overall response rates.

3.6.3.2 Consistent review processes. The operational basis of the NMA separates scientific and ethical review from those considerations undertaken by the research site in order to allow these processes to occur separately but simultaneously.
As Figure 3.6 indicates the concurrent processes of ethical and site specific review.

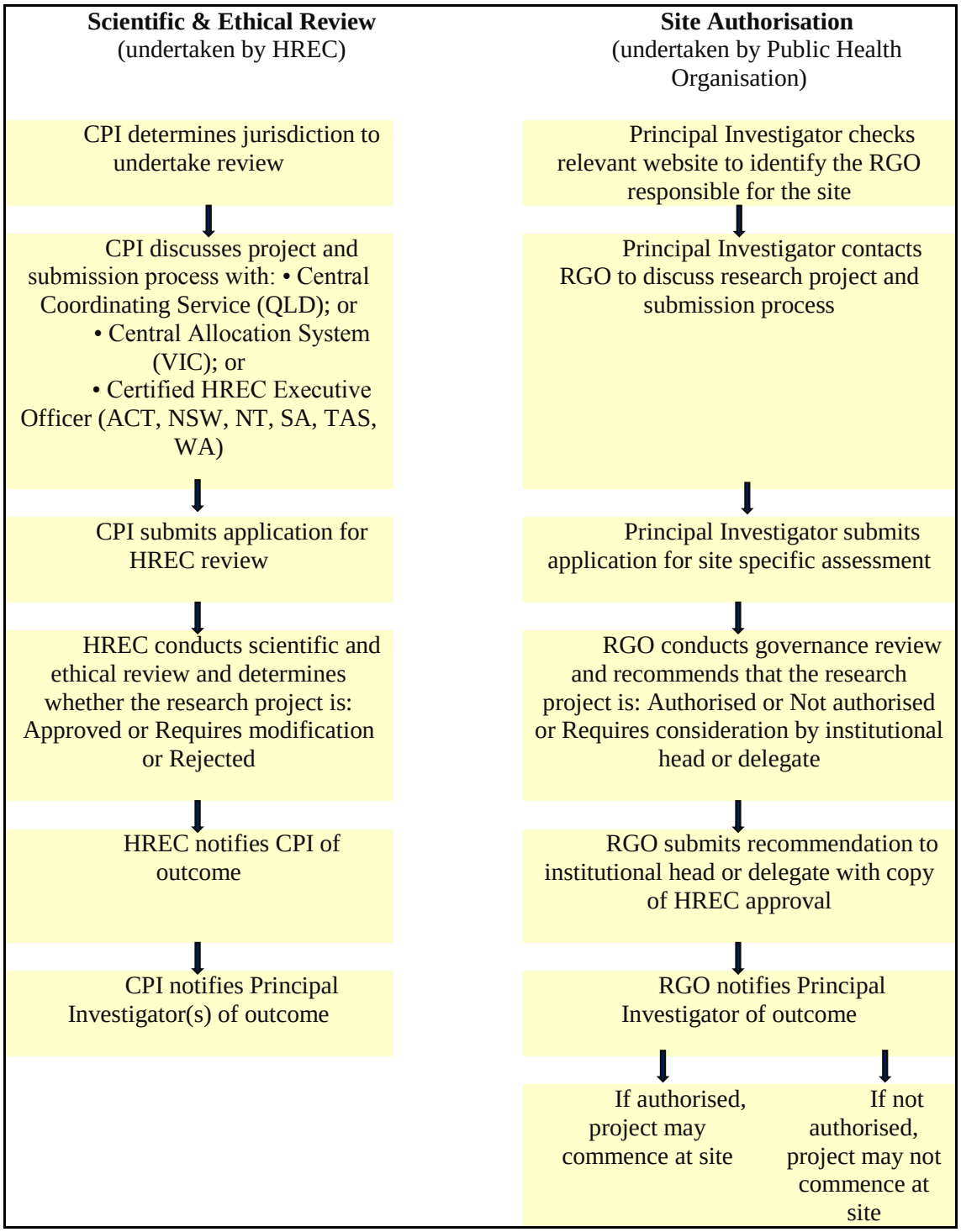


Figure 3.6 Overview of the Scientific & Ethical Review and Site Specific Review

Adapted from *National Mutual Acceptance of scientific and ethical review for multi-centre clinical trials conducted in public health organisations* by Victorian Department of Health and Human Services. (2013).

3.6.3.3 Dedicated IT system. The dedicated IT system links the ethics application process to the participating site specific processes, allowing auto-completion of common data fields and document sharing between the processes. Use of the IT system is compulsory.

3.6.3.4 Personnel roles associated with the NMA. There are four distinct personnel groups directly involved with making a research application through the NMA.

Each participating site has a Principal Investigator (PI) who is responsible for the overall conduct, management, monitoring and reporting of research conducted at an individual site. The PI applies to the Research Governance Officer (RGO) for consideration of the project to be undertaken at that site.

One of the PIs is selected as the Coordinating Principal Investigator (CPI). The CPI is responsible for making the ethics application, on behalf of all participating sites, to the secretariat of the reviewing HREC. The CPI or lead team takes overall responsibility for the submission of the project for ethical and scientific review. The lead site is responsible for ongoing communication with the HREC and with the PI team.

There are also other roles involved with the research review processes that may impact on the timeliness of how the research review proceeds. Within the agency, service departments, such as those departments involved in diagnostic tests, treatment or overseeing the supply of research drugs and devices, may be required to endorse the project. Delays in these endorsements may postpone submission to the RGO, and prolong the time to start-up at the site. Any deferment of authorisation from the Chief Executive Officer (CEO) or delegate will also impact on the study being able to start up in a timely manner.

The NMA is a national model of single ethical review that assumes that the same procedures undertaken by different parties use the same processes. A critical factor in examining this system is to determine how the associations between different parties give rise to the collective behaviours of the system. There are many opportunities to bypass expected behaviours. Figure 3.7 depicts the same process as outlined in Figure 3.6, but has included the associations between the entities.

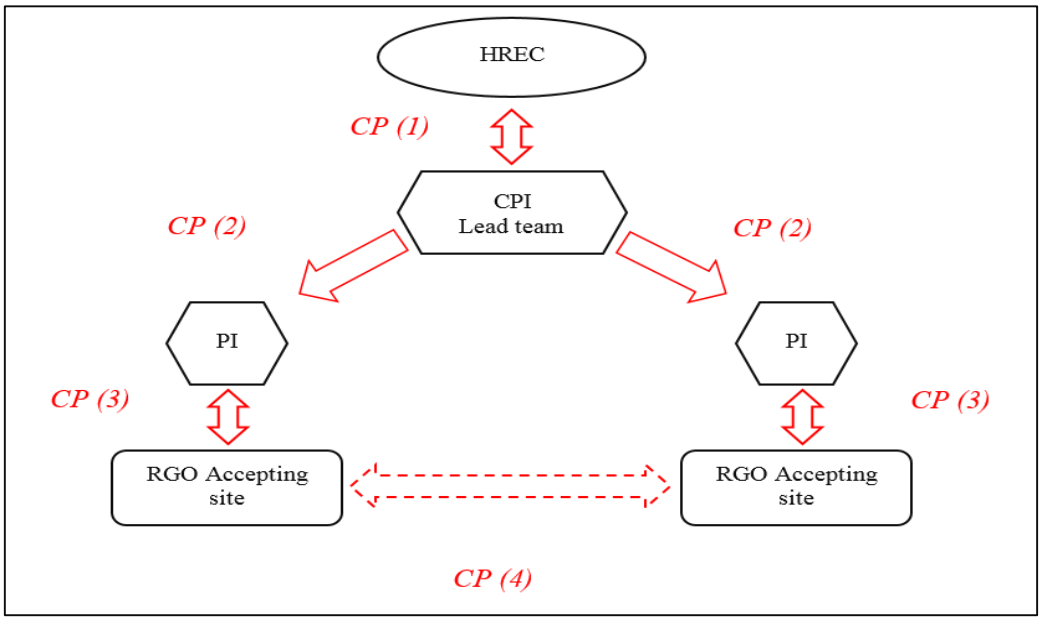


Figure 3.7: Potential change points in the NMA processes

Each of these associations provides an opportunity for change points to develop. Change points (CP) occur when a process deviates from the previous direction. For example, if the HREC administration accepts an application from a lead site that does not have the documents uploaded in the dedicated IT system (CP(1)), then the accepting teams are unable to access the documents through the system (CP(2)). Application to the RGO will also be outside the requirements of the DHHS guidance. Finally at CP (3), the RGO can either require that the PI load all the study documents or continues the process outside the DHHS guidelines. The impact of different choices being made at the change points, means that different research review applications can have diverse outcomes.

3.7 Challenges to a national review model in Australia

In comparison to the UK system, where ethics and governance research reviews are centralised, the Australian approach to a national system has been to retain the locus of control of review at organisational level. The complexity of the Australian healthcare sector makes it particularly challenging to introduce a national model. Provisions of healthcare services from the public healthcare sector involve a multi-faceted web of public, private and not for profit providers, settings, participants and supporting

mechanisms. The multiple stakeholders include: clinicians, consumers, healthcare agencies and service providers as well as academic, financial and business interests, who engage in delivering services within structured legislative and regulatory frameworks. The majority of funding is government, involving both state or territory government and the Australian Government, but oversight of public sector healthcare services is the responsibility of each jurisdiction (Australian Institute of Health and Welfare, 2014).

The degree to which the NMA is accepted as the national process of research review is challenged by several factors: inter-jurisdictional differences; functionality of the single IT platform; competing government strategy and, in Victoria, that public healthcare agencies are independent legal entities.

3.7.1 Inter-jurisdictional differences

Australia, or the Commonwealth of Australia, is a federation of states and territories that have varying levels of regulatory development around research. In addition to Commonwealth legislation, each state and territory has developed their own suite of specific legislation and administrative practices. Advice from the NHMRC noted that, while the process for the ethical and scientific reviews of research is not regulated under law, differing State or Territory requirements may impact the review process. "Relevant areas of law include privacy, guardianship and research involving unapproved therapeutics or the use of human tissues (National Health and Medical Research Council, 2014c, p1).

Each Australian state and territory, for example, has developed different guardianship regimes, which vary widely in their forms of regulation. Guardianship law is the key regulatory mechanism that allows one person or entity to make decisions for another in instances of incapacity or disability. If a multi-site research project involves more than one state or territory, then differences in state guardianship legislation may create impediments in determining an ethically appropriate protocol to cover all participants.

This is exemplified by a legal requirement in NSW that the NSW Civil and Administrative Tribunal (NCAT) must approve a clinical trial before any adult who

cannot consent to their own treatment can take part in that clinical trial. Consequently, there is a strong possibility that start-up of research project, which is designated by NCAT as a clinical trial, and which involves potential participants who cannot provide an informed consent, will be delayed or may not be undertaken at all within NSW because of regulatory requirements (Gattas, 2015; Wiseman, 2015).

There are also inter-jurisdictional differences in research bureaucracy. The submission process varies depending on the jurisdiction to which application for scientific and ethical review is made. The selection of the certified HREC is at the discretion of the applicant but both QLD and Victoria involve a central booking system that assists project allocation whereas other states do not (Victorian Department of Health, 2013a). Consequently, in comparison to the centralised UK system, the NMA has not yet reached a national status.

3.7.2 Competing government strategies

Research is a government priority at both federal and state levels. The Australian Government has undertaken a number of initiatives to improve the clinical trials environment in Australia and to increase Australia's international competitiveness in clinical trials. For example, the 2011 report from the Clinical Trial Action Group (CTAG) [7] promoted clinical trial involvement through collaboration between different parties. This was supported by the Clinical Trials– Jurisdictional Working Group (CT-JWG)[8], which has agreed to a framework for collection of National Aggregate Statistics to provide governments with reliable information on clinical trial activity. A national

[7] The Clinical Trials Action Group (CTAG) was established in response to issues raised in 2009 by the Pharmaceuticals Industry Strategy Group (PISG) to provide advice on reforms to secure Australia's global competitiveness in the clinical trials sector. The CTAG released their report *Clinically competitive: boosting the business of clinical trials in Australia* in 2011. It made 11 recommendations regarding the operations of clinical trials: timeliness, cost recovery, linking into e-health, increasing recruitment, facilitation of national collaboration and coordination and to progress clinical trial issues. The CTAG report is available at https://industry.gov.au/industry/IndustrySectors/PharmaceuticalsandHealthTechnologies/ClinicalTrialsActionGroup/Documents/Clinical_Trials_Action_Group_Report.pdf.

[8] Clinical Trials Jurisdictional Working Group (CTJWG) commenced in 2014 under the auspices of Australian Government Clinical Trials Initiatives to identify and address barriers and enablers to multi-jurisdictional clinical trials. The group involves senior officials from Commonwealth and state and territory health departments, and the NHMRC. Further information regarding the Clinical Trials Initiatives can be found at https://www.australianclinicaltrials.gov.au/

approach would standardise data collection across jurisdictions and provide a means of identifying gaps and barriers and facilitate a quality improvement approach to the sector (Department of Health, 2015).

Although the concept of an efficient and productive research sector is well supported, the complexity of the healthcare sector enables different and possibly competing government strategies, to develop. For example, the principles of the newly developed Academic Health Science Centres (AHSCs) in Victoria may conflict with the NMA. AHSC's encompass a partnership between two or more universities and healthcare providers that concentrates on research, clinical services, and education. Introduction of AHSCs was endorsed in the McKeon report (2013) as part of the recommendation to embed health research and development into clinical practices.

A defining feature of an AHSC is a tripartite mission of delivering high quality research, medical education and clinical care; the parties usually involved include leading universities and hospitals with strong connections to external funding streams. Challenges to the NMA may lie firstly in the inherently competitive nature of the AHSCs and, secondly, in the involvement of a pluralistic mix of governance requirements including health (private and public), academic and business partners. Insurance and contractual issues in private health and universities may differ substantially from those in the public health sector, so it may be difficult to ensure the consistency of compliance to research governance under the NMA. In other words, the AHSC focus on local health care achievement may erode the perceived value of NMA which was intentionally limited to the public healthcare sector.

3.7.3 Operational basis to the NMA

The basis to the NMA is a dedicated IT system developed by an international vendor and operative in several countries including the UK and New Zealand as well as Australia. The system is expected to provide a research submission process and to collect data that can provide indicators of performance at organisational and government levels.

The IT system creates a record for each research application that captures details such as where the research originated and where it was reviewed, type of research, classification, time points and dates through which the National Aggregate Statistics can be created.

Users have raised criticism of the IT system in that it does not accommodate the individual practices of healthcare agencies and the data is not representative. These criticism have led the governments of Western Australia (Government of Western Australia Department of Health, 2017) and New South Wales(Office for Health and Medical Research, 2015) to propose alternative IT system structures.

3.7.4 Consistency of inter-agency risk assessment

Victorian healthcare agencies are independent legal entities established under the *Health Services Act (HSA)* 1988 (Vic) (AustlII). They are each responsible to the Minister for Health for the effective and efficient governance of their health service but they operate under a devolved governance model which allows them to make local decisions to meet local needs (Victorian Department of Health, 2013c). The decision on whether or not a research project may be undertaken at a healthcare agency rests with that agency. Different agencies have different "risk appetites" or differ in the amount of risk they are willing to absorb in order to meet their strategic objectives.

Table 3.4 outlines a cross section of the scope of risks associated with public healthcare agencies undertaking research and clinical trials. This risk diagram was developed by the Victorian Managed Insurance Authority (VMIA) as part of their risk assessment program. VMIA is a Statutory Authority, established by the *Victorian Managed Insurance Authority Act* 1996 (Vic) (AustlII) to provide services as the state's insurer.

Table 3.4: Research risk and risk categories associated with clinical trials

Financial	Infrastructure	Commercial	Operational	Safety	Human Resources	Governance	Strategic
Liquidity – failure to secure timely/adequate funding	Failure of key utilities e.g. electricity	Breach of contract	Poor research outcomes	Laboratory hazards – serious staff injury	Failure to recruit and retain staff to critical roles	Failure to comply with regulatory requirements	Significant change in government research policy
Fraud – misappropriation of funds	Failure of key infrastructure e.g. cooling	Failure to protect intellectual property	Serious errors in research data analysis	Failure to identify and treat adverse clinical outcomes	Failure to verify credentials and scope of practice	Undeclared conflicts of interest	Significant change in regulatory requirements
Over reliance on primary funding source	IT failure	Breach of intellectual property or patent	Damage/loss of key research specimens	Security threat to personnel	Breach of employment contract	Disruption to business continuity	Financial crisis – reduced opportunities for fund raising
Underfunding projects to ensure success rates	Loss of /inadequate communications	Breach of privacy or confidentiality	Lost, damaged or incomplete research records	Staff exposure to genetically modified organisms	Industrial dispute	Ineffective project management	Other?
Other?	Theft	Coercion of research participants	Inadequate consent of research participants	Other?	Other?	Breakdown of key internal or external relationships	
	Other?	Serious research misconduct	Inappropriate disposal of hazardous waste			Approval of a project with unjustified ‘net research risk’	
		Serious research misconduct	Inappropriate disposal of hazardous waste				
		Publication of inaccurate or incomplete information	Inappropriate storage or use of hazardous materials				
		Other?	Failure to procure the right supplies within budget				
			Security breach of information systems				

Reprinted from *Clinical Trials. Risk and Insurance Guide* by Victorian Managed Insurance Authority. 2015. P.8. Retrieved from https://www.vmia.vic.gov.au/

Accordingly, VMIA advise public sector agencies to maintain a risk management framework that aligns with the principles and practices of the *Australian/New Zealand Risk Management Standard (AS/NZSIS0 31000:2009);* the *Victorian Government Risk Management Framework*; and existing legislation such as the *Financial Management Act* 1994 (Vic)) (AustlII) the *Victorian Managed Insurance Authority Act* 1996 (Vic)) (AustlII). Risk management should also be consistent with requirements of the relevant legislation, regulations and guidelines under which clinical trials are conducted (Victorian Managed Insurance Authority, 2015).

Effective risk management is "an integral and essential part of ensuring participant safety in clinical trials" (Victorian Managed Insurance Authority, 2015, p. 6). Potentially, risk management decision-makers at different healthcare agencies might consider the risks associated with each of these items differently as they seek to understand the benefits compared with the risks of being involved with clinical research or trials.

Within the NMA, there is an assumption that the community perspective of one agency is equivalent to another and that a decision from an accredited HREC can apply at all participating healthcare agencies. Literature suggests that cultural considerations may impact on single ethical review. Concerns have been raised that single ethical review is not suitable for studies that involve indigenous populations (Drugge, 2016; Studdert et al., 2010).

3.7.5 Local versus national

Although Australian public healthcare agencies are government funded, they are largely independent legal entities responsible for the welfare of consumers of their services and operating within a financial and regulatory framework. This has the potential to create a tension between meeting the requirements of the NMA and their own local needs and suggests the likelihood of healthcare agencies retaining their local practices, rather than adopting the goals of the national system.

The Victorian *Clinical Governance Policy Framework*, published by the Victorian State Government (Victorian Department of Health, 2008) advises that, at its core, clinical

governance within the Victorian healthcare system is about being accountable for providing safe patient treatments and continuing to improve patient safety. The policy emphasises the standardisation of clinical care within a framework of clinical accountability and financial stewardship. In practice, the primary emphasis of this model rests on the identification and address of local issues and meeting the needs and expectations of the agency patients as service customers.

Interventional studies, or research that manipulates a clinical environment for the purposes of moderating a patient outcome, challenges the tenets of clinical governance. In particular, clinical trials of unapproved medical products or devices are experimental and may involve greater risk to the participating patient, and consequently to the healthcare agency.

Thus in order to protect itself against such risks, healthcare agencies must take steps to ensure that neither they nor any research participants will be harmed through participation in a research project. These deliberations can take time to process, which, in turn, may conflict with the goals of a national system.

3.7.6 The invisibility of the research administrator

The last element to be discussed in relation to the challenges of exploring how organisational research governance behaviour develops in relation to the NMA, involves to the "invisibility" of research administrators. Invisibility refers to the "perceived neutrality of the research administrator. They are paper-handlers, disinterested parties, not key players" (Dunscombe, 2008, p. 8). Dunscombe argues that these roles have tended to be seen as synonymous with either the HREC or the institution and, as a consequence, there has been limited exploration of these positions as distinct entities.

There are few mentions of research administrators in the literature, which supports Dunscombe's claim. However, the concept of administrators as a key role players is now emerging in relation to how research governance practices are undertaken. Lack of inter-organisational standardisation of these roles suggests the likelihood of different decision-making around research review practices.

3.7.7 Why the NMA may confront a healthcare agency

These items suggest the likelihood that the expectation of collaboration between multiple healthcare agencies to meet the goals of a national system goals would challenge the culture of autonomy in healthcare agencies. In principle, these collaborations between those participating in the NMA should benefit all by providing greater efficiency and less duplication. In actuality, the cultural logic of organisational governance model is to emphasise the understanding of local issues to meet the needs and expectations of stakeholders. There is a competing cultural logic between the restrictions of the national goals and the accepted governance model, based on the autonomy of the organisation.

3.8 Research governance and single ethical review

The principles of clinical governance were developed to be the main vehicle for continuously improving the quality of healthcare services provided by individual organisations. Research governance guidelines also promote continuous improvement of research practices and reduction of unacceptable variation in site practices (Department of Health and Human Services, 2013; National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007; Victorian Managed Insurance Authority, 2015). Research governance in this context centred on tasks and measurements of the performance of these tasks.

Single ethical review adds another dimension because of the need to manage the logistics of information transfer between two points within a commonly understood framework. The integration between the activities of different healthcare agencies should create a more effective system and through which a competitive advantage might be achieved. While in the context of a national model, evaluation of research governance centres on the tasks being undertaken it also creates a need to evaluate the value of the tasks. In order to evaluate research governance in the context of the national model of single ethical review, a four pillar approach was used.

3.9 “Four pillars” of research governance

At the turn of the century, the federal government explored how industry development in Australia could proceed through working groups that partnered industry with other

stakeholders or Action Agendas in order to understand specific issues. Research review of multi-site clinical trials had been identified as problematic leading to increasing concerns that Australian research was being disaffected by bureaucratic processes and becoming increasingly uncompetitive on the world market (Fraser, Martlew, & Frew, 2007). The government-endorsed Pharmaceutical Industry Action Agenda (PIAA) was established in 2001 and was later succeeded by the Pharmaceuticals Industry Council (PIC), Australia's peak body for Australia's pharmaceutical and biotechnology industries, in 2006. These bodies promoted the Australian pharmaceuticals industry in relation to global challenges. The role of the Australian Government related to creating an optimal environment for a more successful and viable pharmaceuticals industry to emerge (Lofgren & Boer, 2004).

In 2006 the *Forum on a National Approach to Clinical Trials*, a joint industry and government function, was held to identify possible future development. At the forum, the PIAA presented the Forum with a "four pillar" model for analysing the global attractiveness of the clinical trial environment in Australia and identifying opportunities to improve it.

The four interconnected pillars were identified as timeliness, quality, value and capacity. These attributes were considered as key to building Australian bureaucratic processes conducive for multi-centre clinical trials to be undertaken. Timeliness of start-up focused on efforts to streamline ethical and scientific approval of multi-centre trials. At the time of the forum, timeliness efforts largely focused on incoming single ethical review initiatives, which began in 2007. Possible measures that could address limitations in Australia's ability to quantify environmental quality involved education and accreditation of researchers and industry. The forum noted that value of a clinical trial is best determined by a costing model that recognises both the cost of undertaking a trial as well as market growth rates, pharmaceutical reimbursement and Government incentives. Measures of capacity describe overall participant recruitment numbers but also the relative capacity to produce data in niche areas, such as early phase clinical studies and hard-to-find study subjects (Department of Industry, 2006).

3.10 Summary

Chapter Three examined the context of the study, the Australian public healthcare sector and the setting in which multi-site clinical trials take place. The effect of the environmental forces on research governance was discussed at length. Many of the Australian research reforms have developed in response to influences from the broader environment.

Clinical trials involve a number of unusual characteristics, both in their structure and in the nature of their business operations. Clinical trials are part of a developmental pipeline that aims to market a new product, thus there is a strong business focus especially on the timeliness of the start-up and accuracy of data collection. They offer both benefits and risks. Benefits include innovative healthcare and financial advantages but there are many risks associated with experimental products.

Globally, unprecedented increases in commercial, multi-site clinical trials resulted in concerns about inconsistent research review processes. These concerns led to pressures for global standards in the conduct of research on human subjects. Identification of bureaucratic delays in review processes of multi-site research, for example, led to the instigation of single ethical review of multi-site clinical trials. Most countries wishing to host clinical trials have initiated reform of their existing regulatory approaches and bureaucratic processes.

To remain internationally competitive, Australia is undertaking research reforms to provide an optimal clinical trial environment. These reforms focus on rationalising research bureaucracy and harmonising research processes between research entities. The NMA approach to single ethical review in public health research is an example of these strategies.

The principles of single ethics review of multi-site research and how those principle relate to different models of review were presented. The development of national model of single ethical review of multi-site research in Australia and the challenges to a national review model in Australia were then discussed.

The many and varied environmental elements impacting on the connection between the NMA and the research governance practices of Victorian public healthcare agencies suggest that any evaluation will also be multi-faceted. The concept of evaluating research governance through "four pillars" of timeliness, quality, value and capacity was introduced. The four pillar model is used as the basis to the conceptual model presented in Chapter Four.

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CHAPTER FOUR: THE CONCEPTUAL FRAMEWORK AND RESEARCH QUESTIONS

4.1 Introduction

The conceptual framework is presented in this chapter to explain the key drivers that influence a public healthcare agency decision-making in relation to the National Mutual Acceptance (NMA) of single ethical review of multi-site clinical trials. The theoretical basis to the thesis, presented in Chapter Two, described the complexity of analysing corporate governance (Armstrong, 2004; Armstrong et al., 2005 ; Crow et al., 2013; Edwards & Clough, 2005; Hough et al., 2005), with the inference that any analysis of research governance, as a sub-section of corporate governance, is also likely to be complex.

Institutional isomorphism theory was used to provide the theoretical foundation of the conceptual model to enable an exploration of governance decision-making as a social structure. It suggests that corporate governance involves values and behavioural reasoning that originate in the institutional context (Scott, 2014b). The term "isomorphism" refers to the degree to which organisations appear similar to their peers within a similar environment. Isomorphism in the social sciences is a constraining process that forces one unit in a population to resemble other units that face the same environmental conditions (DiMaggio & Powell, 1983).

This Chapter has drawn on discussions in previous chapters. The literature review in Chapter Two outlined the theory of Institutional Isomorphism which describes how organisations aim to appear legitimate to their stakeholders and develop similarity in processes and structures to their peers when faced with the same constraints. There are three types of isomorphic influence: coercive, mimetic and normative. The inference from Institutional Isomorphism theory is that healthcare agencies involved with the NMA will also tend towards similar structures and processes in order to appear to have a legitimate role in the system.

The preceding chapter, Chapter Three, described how the competitive nature of the global research environment required Australian governments to evaluate the attractiveness of Australia's research environment through timeliness, quality, value and capacity (Department of Industry, 2006), and also led to the instigation of the NMA into the public sector. For public healthcare agencies, the introduction of the NMA involves the requirement to observe the national model of single ethical review in addition to obligations to comply with conventional clinical and financial governance conditions (Victorian Department of Health, 2008)(Victorian Department of Health, 2008)(Victorian Department of Health, 2008)(Victorian Department of Health, 2008)(Victorian Department of Health, 2008)(Victorian Department of Health, 2008)(Victorian Department of Health, 2008)(Victorian Department of Health, 2008)As observed by Franck et al. (2004), challenges can arise in implementing a national system where addressing specific local issues may conflict with the goals of a consistent national model.

This chapter is structured as follows. Section 4.2 defines organisations, institutions and institutionalisation. This is followed by a discussion of the theoretical framework in Section 4.3. Section 4.4 presents facets of the association between research governance and the NMA. Section 4.5 outlines the four pillars of research reform as measures of the effectiveness of research governance. The conceptual framework is outlined in Section 4.6, after which section 4.7 discusses the research questions and hypotheses. Section 4.8 concludes the Chapter.

4.2 Organisations, institutions and institutionalisation

4.2.1 Organisations

Organisations are entities which involve a collective goal shared by many people that is linked to an external environment. They are comprised of many elements, such as rules, norms, or beliefs, some of which derive from on-going interaction and others being borrowed from their environment (Scott, 2008). Organisations conform to external pressure by adopting appropriate rules and structures (Meyer and Rowan, 1977). Thus organisations are themselves systems and can be analysed as such but they can also be actors in larger systems (Scott 2016).

4.2.2 Institutions

Institutions provide the context for organisations to function. Institutions are comprised of "regulative, normative and cultural-cognitive elements that, together with associated activities and resources, provide stability and meaning to social life" (Scott, 2014a, p.56). For example, the military is an institution that encompasses those structures, services and personnel involving the armed forces. It is not a specific building or physical location but those involved with the military are constrained by the military's institutional rules and regulations. Similarly, clinical research could be viewed as an institution aimed at manufacturing the scientific foundation for clinical practice.

According to Scott's three pillar model (2014a), discussed in Chapter Two, institutions impact organisations through regulative, normative, and cognitive elements. The regulative pillar focuses on the ability of institutions to constrain and regularise behaviour through rule setting, monitoring and manipulating sanctions, rewards and punishment in order to influence conduct. For example, clinical trials are required to be listed on a public clinical trials register before the enrolment of the first subject (International Committee of Medical Journal Editors, 2004). The institution of clinical research has established its own regulative boundaries of acceptable behaviour in that a clinical trial that was not entered on a clinical register would not be published.

Normative rules prescribe rights and privileges as well as responsibilities and duties through which goals, such as winning and successful behaviours, are defined. Within the institution of clinical research, the normative pillar is represented by the widespread adoption of Good Clinical Practice (GCP) which provides international quality control for clinical trial practices. GCP is embodied into the expectations of clinical trials sponsors, so GCP training has become a prerequisite of all trial personnel (National Health and Medical Research Council, 2011a).

Scott's cultural-cognitive third pillar states that meaning of shared concepts occurs through external cultural frameworks. The widespread acceptance of evidence-based decision-making in health gives credence to randomised clinical trials as the "gold standard" in providing medical evidence to multiple stakeholders.

4.2.3 Organisational institutionalisation

Institutionalisation refers to the socio-cultural process of embedding particular concepts, beliefs, norms or modes of behaviour within an organisation (Scott, 2014b). Meyer and Rowan (1977) proposed that institutionalism involves the processes by which social processes and obligations come to take on "rule-like status in social thought and action" (p.341). DiMaggio and Powell (1983) described the similarity of organisations within the same environment as occurring through isomorphic influence. The logic underlying institutionalism relates to the need for survival, thus an organisation conforms to expected laws and rules to seek the attendant rewards and to avoid sanctions (Scott, 2014b).

Scott's three pillar model (2014a) has suggested that institutions are dynamic. While the regulative, normative and cultural-cognitive elements might be simultaneously engaged, they bring different bases of order and compliance, varying mechanisms and logics and alternative rationales for establishing legitimacy claims that might impact an organisation differently. This interplay suggests that organisations faced with multiple and, potentially conflicting stakeholder requirements, need to strategize their responses. For example, clinical decisions need to accommodate budgetary constraints as well as medical priorities.

Scott further noted that the process of institutionalisation is not straightforward. Organisations under pressure to adopt particular structures or procedures, that conflict with coexisting requirements, may opt to decouple from the pressure or respond in a ceremonial manner, making changes in their formal structures to signify conformity, but then buffering internal units, allowing them to operate independent of these pressures. (Scott, 2014a). This decoupling is similar to observations made by Ashworth et al. (2007) that organisational conformity can be divided into compliance, moving in the direction that is consistent with isomorphic pressures, and convergence, where all organisations in a field grow to resemble each other. Convergence can decouple from compliance. Institutionalisation is a cumulative process that develops over time and through different cultural-cognitive mechanisms.

4.3 Theoretical basis

4.3.1 Institutional isomorphism and the NMA

Institutional isomorphism theory traverses the academic fields of economics, sociology, political science and organisational theory (Scott, 2004) to create the premise that organisations are deeply embedded in a wide-ranging institutional context (Powell 1988; DiMaggio & Powell 1991). The institutional environment is the source of both legitimisation and constraints of organisational activities (Meyer & Rowan 1977). Institutional theory is based on how organisations achieve legitimacy, and thus survival, through the social construction of reality. The relevance of institutional theory to the analysis of how public healthcare agencies respond to the NMA was initially derived from this view.

The theoretical basis to the conceptual framework is Institutional Isomorphism. As discussed in Chapter Two, this theory involves perception of organisations as social entities which tend to develop similar characteristics through isomorphic mechanisms (DiMaggio & Powell, 1983; Meyer & Rowan, 1977). Isomorphism occurs when the structure or processes of one organisation develops similarity to another. This is driven less by the desire for efficiency but the desire to appear to be behaving in a legitimate or appropriate manner (DiMaggio & Powell, 1983). The key concepts of this theory include organisational legitimacy, organisational fields and mechanisms of isomorphism.

4.3.2 Organisational legitimacy

Organisational legitimacy is a critical but somewhat abstract concept that involves alignment of some aspect of an entity and a social system of norms, values, beliefs, and definitions. It is conferred by those outside the organisation who have legitimacy-determining power (Pfeffer & Salancik, 1978) but it is also dynamic, reflecting the need of organisations to perpetuate acceptance in a changing society. Legitimation or legitimisation refers to the process of providing legitimacy by confirming something as acceptable and normative to a group or audience.

The theory of Institutional Isomorphism states that, in order to function effectively in their environment, organisations must conform to the prevailing rules and belief

systems (DiMaggio & Powell, 1983). Acceding to pressure to be similar to others within a specific organisational field makes the organisation appear legitimate (Deephouse, 1996; Suchman, 1995).

Legitimacy is a social construct based on a reaction of observers to their perception of the organisation. According to Meyer and Rowan (1977), as social processes, obligations and actualities become commonly accepted, they take on a rule-like status in social thought and action. Hence, legitimacy provides the primary incentive for the adoption of institutionalised practice in order to provide stability in the face of uncertain markets or changing technologies (Meyer and Rowan, 1977) and is a fundamental condition of an organisation's social existence (Scott, 2014b). It is "tightly connected to the concept of institutions, which are enduring social structures and processes that give order and meaning to life. Legitimacy is a necessary characteristic of a well-established institution" (Hurley & Sá, 2013,p. 159).

Within investigation into organisational behaviour, the concept of legitimacy plays an important role. It follows that an organisation is acting in a legitimate fashion if its activities are consistent with relevant stakeholders. The relationship between isomorphism and organisational legitimacy was tested in a study of the strategies of commercial banks (Deephouse, 1996). The study found that legitimacy to one audience may not mean legitimacy to another.

4.3.3 Legitimacy within the complex, multi-level health sector

The concept of legitimacy is particularly relevant in the complexity of public healthcare service provision and management of multiple stakeholders. The many different components involved in a single care episode, such as inpatient and outpatient departments, clinics, laboratories and diagnostic, surgical and specialist units as well as non-clinical functions and the involvement of non-public organisations, introduce a plethora of possibly inconsistent goals[9]. Accordingly, a positive clinical outcome might conflict with financial goals if a clinical care episode exceeded the allocated budget.

[9] A recent study of UK healthcare stakeholders involved in the implementation of a common IT system found that stakeholders wore multiple "hats" leading to conflicts of interest which impeded the success of the program. See Currie, Wendy, Pouloudi, Nancy and Whitley, Edgar A. (2016) Entangled stakeholder roles and perceptions in health information systems: a longitudinal study of the UK NHS N3 network. Journal of the Association for Information Systems, 17 (2). pp. 107-161. ISSN 1536-9323

Public healthcare also involves both federal and state and territory governments operating within a model of multi-level governance that increasingly positions governing on public matter as a shared domain involving government, differing public authorities, non-governmental actors as well international organisations. For example, foreign policy is a dominant feature of any national strategy impacting on areas such as trade, economic and migration policies. This may lead to potential incongruence between aims of political strategy and the operational goals of a public service.

4.3.4 Legitimacy of research

Literature suggests that organisational survival depends not just on material resources and technical information, but also on the organisation being perceived as acceptable and credible, or in other words, legitimate (DiMaggio & Powell, 1983). Public healthcare is multifaceted, involving the provision of numerous services and multiple stakeholders. The multiplicity of services suggests that measures of legitimacy may apply differently to distinct components of the organisation.

Anecdotally, there is some uncertainty about how important research is regarded in the public healthcare sector. Federal strategy requires that healthcare agencies comply with the NMA but governance of research is not currently included in the Victorian clinical governance policy framework (Victorian Department of Health, 2008). The inference is that this may lead to inconsistencies in the perception of value of research in healthcare agencies. Thus, it is anticipated that the degree to which research is viewed as a core agency activity is expected to provide the strongest predictor of NMA compliance and remain significant at all other points of measurement.

4.3.5 Legitimacy of the NMA

Literature discussing experiences in the United Kingdom of adapting programs from a local to centralised focus highlighted the obstacles in trying to meet the needs of both national and local models (Ashworth et al., 2007; Franck et al., 2004; Howarth et al., 2008). Current industry data from Australia also demonstrates evidence of inconsistent regulatory timelines (Hasthorpe, 2014; Health Outcomes International, 2015).

4.3.6 Isomorphic pressure and legitimacy

Figure 4.1 unpacks the connection between Institutional Isomorphic theory and the intended outcome of legitimacy. Organisations are driven towards legitimacy through their quests for endorsement of a social authority. Legitimacy may be gained though one or more government, public or professional endorsements.

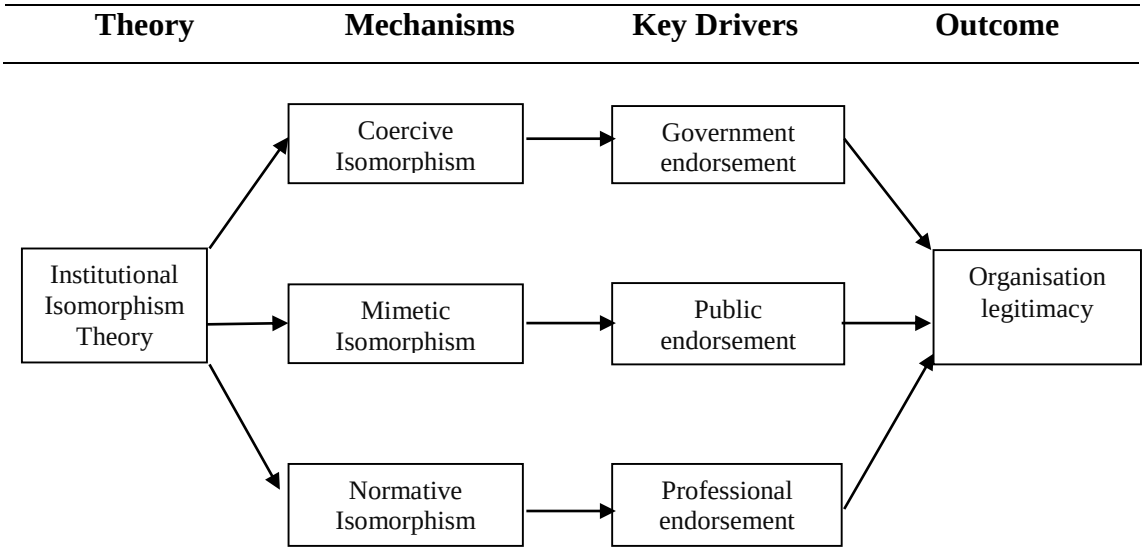

Figure 4.1: How isomorphic pressures lead to legitimacy

It is important to note that one endorsement does not automatically imply others. An organisation could achieve legitimacy in one area, such as government endorsement if it fulfilled compliance requirements, but complications may arise if such compliance is achieved using processes and structures that were not in keeping with other drivers. For example, within the NMA, researchers may apply to any accredited HREC through a dedicated IT system (government endorsement) but organisations that successfully behave outside the dedicated IT system may be mimicked by others (public endorsement).

4.3.7 Organisational fields

Organisational fields are defined as "sets of organizations that, in the aggregate, constitute a recognized area of institutional life; key suppliers, resource and product consumers, regulatory agencies, and other organizations that produce similar services or products" (DiMaggio & Powell, 1983, p.148). The concept is elemental in Institutional

Isomorphic theory, as it defines and delimits the activities of the organisations and other social actors within that field (Machado-da-Silva et al., 2006).

Australian public healthcare is driven by the implementation of safety and quality systems that standardise the quality of health. While the provision of healthcare is complex and there are multiple stakeholders, this suggests that the organisational field around standard care is driven by service provision and provided within allocated Government funding.

The concept of organisational field is of importance in distinguishing research conducted in a public healthcare agency from the standard healthcare structures. The majority of public health funding is provided by the Australian Government to state and territory governments for their spending on public hospitals. Research that is funded by commercial sources or competitive grants is less consistent, depending on the number and types of studies being undertaken. Externally funded research requires organisational financial managers to take on different responsibilities from the management of government budgets.

Additionally, while both standard care and research involve similar sets of entities that constitute recognised areas of institutional life, clinical trials involve additional regulatory bodies or those bodies being involved in a different capacity. In relation to standard clinical care, the Australian Therapeutic Goods Administration (TGA) and the USA Food and Drug Administration (FDA) endorse the quality of marketed pharmaceuticals but in relation to an experimental medical product, both administrations are instrumental in determining the suitability of the product for marketing.

4.3.8 Mechanisms of isomorphism

Three key mechanisms of Institutional Isomorphism theory derive from coercive, mimetic and normative pressures. Organisations depend on stakeholders to acknowledge them as more “meaningful, predictable, and trustworthy”(Suchman, 1995, p. 575). Stakeholders proffer or withhold their support in return for the organisation

producing an output valued by the stakeholder (goods and/or services). Hence organisations depend on stakeholders for survival.

4.3.8.1 Coercive pressure. Coercive isomorphism is that which stems from the cultural expectations of legitimacy of the society in which the organisation functions (DiMaggio & Powell, 1983). Public healthcare agencies rely heavily on government funding(Australian Institute of Health and Welfare, 2014) The dominant stakeholder in the public sector is government as the primary funder acting through coercive pressure.

The NMA is a government initiative directed specifically at the publicly funded health sectors of each State and Territory (Commonwealth Government, 2012) and therefore able to pressure the public healthcare sectors of the states and territories to participate. However, there is limited ability to enforce full conformity.

The NMA was introduced as one of the measures intended to improve performance in Australian research review. Although not centralised to the extent of the UK model, the NMA has prescribed a specific application process that includes specifying which accredited HRECs are able to provide a single ethics review and separating the HREC review from research site's own assessment of its capacity to undertake the project.

Literature indicates that adapting from organisational specific to an intra-organisational system can be problematic for organisations, particularly when addressing specific local issues conflicts with the goals of a broader approach. Further troubles may arise when other relationships, such as with universities or the private sector are not included in the larger system (Franck et al., 2004).

It is not difficult to find indications of weaknesses in the review processes surrounding multi-site projects: researcher frustration with the duplicative behaviours of ethics committees (Dickson, 2004; Webster & Temple-Smith, 2013; White et al., 2016); concerns that delays in research review cause financial constraints and loss of opportunity (Clinical Trials Action Group, 2011) and blurring of HREC and organisational responsibilities (Gorman, 2011). Furthermore, advice from the NHMRC states that responsibility for the integrity of the research, conduct of researchers and the ability to take action in response to inappropriate conduct resides at the level of the

organisation undertaking the research (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007) and, in Victoria, public healthcare agencies are independent legal entities responsible for the welfare of the recipients of their care (Victorian Department of Health, 2013c). These factors suggest that the coercive power of the NMA is not straightforward.

4.3.8.2 Mimetic pressures. Mimetic isomorphism is the mechanism whereby organisations deliberately model themselves on other organisations in order to gain legitimacy (DiMaggio & Powell, 1983). Environmental uncertainty increases the likelihood of mimetic behaviours. The pressure to copy or emulate the activities, systems, or structures of other organisations, is particularly strong in times when goals are ambiguous or when organisational technologies are poorly understood (DiMaggio & Powell, 1983). In this situation, mimicking another organisation, which is perceived as successful or legitimate, becomes a "safe" way to proceed. Such mimetic behaviour is rational because it conserves costs of searching for actions to reduce the uncertainty being faced by the organisation (Meyer & Rowan, 1977). Literature indicates that, in times of uncertainty, mimetic isomorphism is likely to provide the strongest impact.

According to Frumkin and Galaskiewicz (2004), USA public sector organisations are consistently more susceptible to all three types of institutional isomorphism forces than for-profits and non-profits organisations. They also found that mimetic influence has greater impact. Furthermore, they found that mimesis of peers resulted in government organisations becoming more centralised, more formalised, and more departmentalised.

Other scholars also supported the impact of mimetic influence at an organisational level (Barreto & Baden-Fuller, 2006; Ginn, Shen, & Moseley, 2009; Haveman, 1993); at department level (Campion & Gadd, 2009) and at individual manager level (Villadsen et al., 2010). Valladsen et al. (2010) emphasises that mimetic decision-making requires decision-makers to deliberately seek information about other organisations in order to imitate them.

Mimicry also helps to preserve the status quo among comparable organisations, stabilising the leader positions while raising the possibility of failure for those that act differently. Thus, an organisation conforms to strategic behavioural norms in order to

demonstrate that it is acting in an acceptable manner and that social actors should evaluate it as legitimate (Meyer & Rowan, 1977).

Persistent variety in meeting expected timelines, suggests that uncertainty around the NMA and the processes that support it remains (Haines, Sansom, & Whittall, 2016; Hasthorpe, 2015; NSW Ministry of Health, 2013). Both the findings from academic literature and sector data suggest that mimetic isomorphism should be a powerful influence in how healthcare agencies managed their compliance to the NMA.

4.3.8.3 Normative isomorphism. Normative pressure is associated with professionalisation, that is, pressures brought about by a profession establishing a cognitive base (DiMaggio & Powell, 1983). Pressures can be exerted through formal education or professional networks. The end result is that personnel from similar backgrounds will approach problems in much the same way.

The degree to which normative isomorphism, or pressures from professionalisation and formal training, affects organisational behaviours has been much promoted in institutional isomorphism theory (DiMaggio & Powell, 1983; Meyer & Rowan, 1977). Theorists argue that people from the same educational backgrounds will approach problems in similar ways. In other words, inter-organisational socialisation such as professional networks or inter-organisational hiring will reinforce norms and routines.

There is limited literature that examines normative isomorphism as a sole influence. Ashworth et al. (2007) observed evidence to suggest that the government sought to build normative pressures as a support to the coercive impact of new legislation. Campion and Gadd (2009) noted that clinician participation in a new clinical treatment may have been related to continuing education, workforce socialisation and professional societies that supported the treatment. In that study, normative influence was paired legislation changes (coercive) to develop clinical practices changes in keeping with a pilot or expert site (mimetic).

Teodoro (2014) argued that executives who belong to a specific profession ought to manage differently from similarly situated executives who do not. The study analysed the degree to which local government water utilities in the USA complied with US *Safe*

Drinking Water Act 1974 (SDWA). Using normative isomorphism as a theoretical base, he described how utilities that were led by engineer executives were more likely to comply with the Act, whereas non-engineer executives were less likely to comply. He attributes the difference in executive approach to the professional norms of the engineering profession.

Unlike a recognised profession like engineering, research regulators have different experiences, roles and responsibilities. They are recruited from a variety of backgrounds and the same employment title can involve different activities, and status within the agency hierarchy. There is no single accredited qualification required to be employed with a research administrator role.

Traditionally, research administrators are seen as a being "caught between the frequently conflicting goals of the research scientist and the research organization" (Kaplan, 1959, p. 31). There has been a lack of clear boundaries and role definitions (Dunscombe, 2008). The Victorian state government offers some networking opportunities for governance personnel by hosting events and forums where aspects of research review processes are discussed (Victorian Department of Health, 2015).

While there is some overlap between the three mechanisms, they derive from different conditions. Mimetic and normative processes derive from internal drivers, whereas coercive isomorphism is linked to the environment surrounding the organisational field (Frumkin & Galaskiewicz, 2004). It could reasonably be expected that the dominant isomorphic mechanism in public health care organisations would be coercive. Coercive pressures can be seen clearly in the NMA through the use of Memoranda of Understanding between parties which explicate organisational responsibilities (Victorian Department of Health and Human Services, 2016a). Literature, however, has found that government organisations are susceptible to other isomorphic influences (Frumkin & Galaskiewicz, 2004) and that responses to coercive influence can vary (Ashworth et al., 2007). Hence, the conceptual model developed for this study includes coercive, mimetic and normative isomorphism.

4.4 Corporate governance of research and the NMA

Research governance roles and responsibilities of organisations undertaking research are outlined in the *Australian Code for the Responsible Conduct of Research* (the Code) (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007). The overall philosophy of the Code is to create a culture of continuous quality improvement in research through promotion of research integrity and providing guidance to institutions and researchers in responsible research practice. Organisations are expected to develop their own research governance framework based on the Code. Section 1.2.1 of the Code states that each institution "should provide an appropriate research governance framework through which research is assessed for quality, safety, privacy, risk management, financial management and ethical acceptability"(National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007, p. 1.3). At a minimum, baseline risk management requires formal endorsement of a given project by all the researchers involved as well as supporting departments.

Research can involve many service departments. For example, commercial clinical trials evaluating an innovative product often involve services such as pharmacy, medical imaging and pathology that need to balance their clinical service requirements against research requirements. Endorsement from supporting service departments involves balancing their research requests against clinical needs to confirm that the required services can be provided with no disadvantage to the agency.

In comparison, the success of the NMA is measured in aggregated statistics, including overall research volume and the timeliness of review. Re-orienting clinical research review towards a national system requires all participating organisations to adhere to standard practices so that the process of single ethical review proceeds in accordance with the formal guidance. The NMA is also a system that involves sets of interacting elements that impact the practices of others. Behaviour that falls outside the system can be problematic for those "downstream" and can negate the effectiveness of the system.

While the national system does not negate the responsibilities of individual agencies, it adds the expectation that the individual agencies will work towards the goals of a

consistent national model. This requires not only the applicant and the research office personnel to recognise the goals of the national model but that recognition applies to all those involved with the undertaking of the project.

Thus the measures of research governance undertaken in relation to multi-site clinical trials reviewed through the NMA system of single ethical review relate not only to the measure outlined in the Code but also to aggregate measures of the whole of the NMA.

4.5 Four pillars as a measure of governance

The four pillar model identifies measures of research activity that can be used to quantify elements of the research environment.

1. *Quality* refers to the need for Australia to provide quality data.
2. *Timeliness* of clinical trial steps are critical to retaining a business momentum.
3. *Value* means that *g*lobal decision-makers need to consider the direct cost of undertaking a trial in Australia as well as the value of the product within a commercial environment and, to a lesser extent, government incentives for industry investment.
4. *Capacity* includes both the absolute capacity to recruit patients and the relative capacity to produce data in niche areas, such as early phase clinical studies and hard-to-find study subjects.

Since this model was outlined in the *Report on the Forum on a National Approach to Clinical Trials* (2006), further guidance from the NHMRC has been released and the NMA commenced. Table 4.1 lists the key attributes of each pillar, with examples of organisational behaviour that indicate support of the pillars which have been developed using both the NHMRC *Australian Code for the Responsible Conduct of Research* (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007) and NMA guidance provided by the Victorian DHHS (Victorian Department of Health and Human Services, 2013).

Table 4.1 Attributes of research governance in relation to the four pillar model

Pillar	Key attribute	Examples of evidence
Quality	Excellence	Evidence of education and training e.g. in Good Clinical Practice Certification/accreditation programs for researchers, institutions and ethics committees Interjurisdictional certification of key roles Evidence of agency research strategy regulatory in accordance with current guidance Evidence of regulatory compliance Audit and reporting systems
Timeliness	Single ethics review	60 day NMA benchmark performance e.g. speed of ethics review Speed of site specific assessment Speed of recruitment
Value	Costs	Use of standard research agreements Costing models and transparency of budget
Capacity	Competence	Increased recruitment capability Organisational research strategy Profile of organisational research Numbers of staff involved in research

Adapted from: *Report on the Forum on a National Approach to Clinical Trials* 2006, Canberra and the *Australian Code for the Responsible Conduct of Research (ISBN 1864964383* by the Commonwealth of Australia. 2007. Canberra.

4.6 Conceptual Framework

Development of the conceptual model was based on work by Watts and Mead (2005) who employed Institutional theory to develop a crossover framework to evaluate the practice of benchmarking.

4.6.1 Development of the conceptual model

The conceptual model was used in this context to provide an organising structure for the research design and methods that guided the development and testing of the study hypotheses and propositions. It helped explain the study results by positioning them in the context of public healthcare agency decision-making.

The model brought together two conceptual domains: that the effectiveness of multi-site research governance can be measured using four pillars and that organisations tend towards similarities in structure or behaviour to improve their chances of survival in an environment. The conceptual domains are supported by three constructs:

- Individual demographics of: age (years); education; gender; main role; organisational level; years worked in current role and study participant location
- Perceived importance of research to healthcare agencies
- Perceived impact of the NMA as an isomorphic force towards organisational legitimacy

Elements of corporate research strategy, isomorphic mechanisms, the legitimacy drivers of the NMA and the associations between the elements were then drawn from the constructs.

1. Corporate research strategy of healthcare agencies concerns the overall direction of the research goals of the healthcare agency. Of particular significance was the importance that agencies attribute to research. Literature suggests that the degree of dependency that one entity has on another impacts the strength of isomorphic influence (DiMaggio & Powell, 1983). In the case of multi-site research, this suggests the likelihood for greater support of the NMA when agencies attribute research as a core component of their activities. Importance was determined by observable behaviour, such as written advice on research review. Phase Two interview participants were invited to indicate which organisational behaviours were conducive to incorporating research as a core activity.

There are two associations to the element corporate research strategy. One related to the impact an agency's regard for research had on the strength of the isomorphic mechanisms. The second related to the expectation that demographics of the research participant would influence their perceptions of corporate research strategy.

2. The second element, isomorphic mechanisms, was created by applying measures of research governance (quality, timeliness, value and capacity) to the three isomorphic influences: coercive, mimetic and normative. This defined the theory of isomorphic influences in terms of a practical application.

The conceptual model proposed three associations to the element Isomorphic mechanisms. One related to the impact of agency's regard for research on the strength of the isomorphic mechanisms. A second linked the individual Isomorphic Mechanisms with the NMA Legitimacy Drivers.The third related to the expectation that demographics of the research participants would influence their perceptions of corporate research strategy.

3. NMA legitimacy drivers are those forces that endorse the impact of the isomorphic influences. Government endorsement of legitimacy is driven by coercive isomorphism to achieve timeliness. Public endorsement is driven by mimetic isomorphism to address stakeholder perception of organisational value and capacity. Professional endorsement is driven by normative isomorphism to achieve perceptions of quality. Some examples of the legitimacy associated with each driver are provided.

There are two associations to the element Isomorphic mechanisms. One related the NMA Legitimacy Drivers with the individual Isomorphic Mechanisms. The second related to the expectation that demographics of the research participants would influence their perceptions of corporate research strategy.

Figure 4.2 presents the conceptual model in which the definition of research governance practice is conceptualised as a journey from current agency specific processes to a strategic focus.

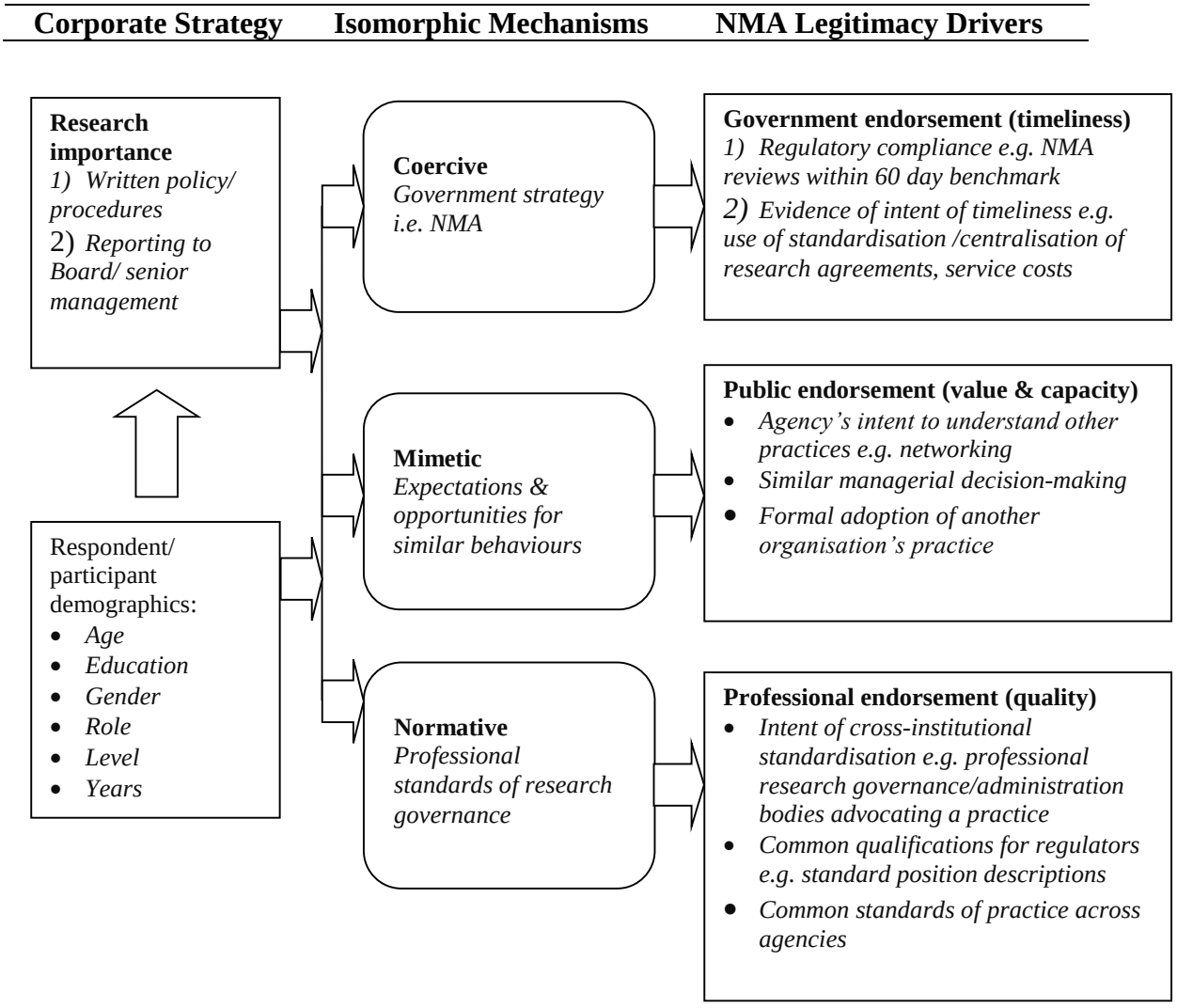

Figure 4.2: The conceptual crossover of isomorphic theory and NMA

4.7 Research question, propositions and hypotheses

4.7.1 Research question

This study was undertaken to describe how the National Mutual Acceptance (NMA) has influenced research governance practices in Victorian public healthcare agencies involved in multi-site clinical trials, focusing on both the adoption and operation of reform. It was developed to address the following question:

> What are the coercive, mimetic and normative pressures that influence public healthcare agencies in Victoria to comply with the National Mutual Acceptance?

4.7.2 Propositions

The model outlined in Figure 4.2 gave rise to several propositions. The first proposition was that the adoption of the NMA was positively related to perception of significance of research to the organisation. Based on findings from the literature, it was assumed that an organisation would only act in an area in which it was important to appear legitimate (DiMaggio & Powell, 1983; Scott 1995; Suchman, 1995). The second proposed that the operation of research governance reform was positively related to: perceptions of the NMA having authority (Coercive isomorphism); the need to compare practices against peers (Mimetic isomorphism) and endorsement of research governance standards (Normative isomorphism) (DiMaggio & Powell, 1983). It was also proposed that respondent demographics would influence their perception of the impact of the NMA. In particular, it was expected that that the respondent role would be significant. Based on literature such that the effect will be stronger for Regulators.

The propositions drawn from the theory supporting the conceptual model are that:

> If the NMA is viewed as legitimate, health care agencies should show recognition of research activity
> If the NMA is a coercive influence, health care agencies should show evidence of support of the NMA
> If the NMA is a mimetic influence, health care agencies should collaborate with other agencies and learn about their practices

If the NMA is a normative influence, health care agencies should participate in professional standards.

4.7.3 Hypotheses

The following hypotheses were developed:

Hypothesis 1 (H1) – that in relation to research governance reform, adoption of the NMA was positively related to:

H1a Organisational recognition of research activity (legitimacy)

Hypothesis 2 (H2) – that in relation to research governance reform, the operation of the NMA was positively related to:

H2a Acknowledgment of the authority of NMA (Coercive isomorphism)

H2b Perception of the need to compare with peers (Mimetic isomorphism)

H2c Endorsement of research governance standards (Normative isomorphism)

Hypothesis 3 (H3) – that in relation to research governance reform, perception of adoption and operation of the NMA was positively related to respondent role, such that the effect will be stronger for Regulators than other demographics

4.7.4 Phase One : survey data

The survey instrument was developed specifically for this study by the author. The survey sections were based on Institutional Isomorphism as presented by DiMaggio and Powell (1983) and the survey constructs were organisational field and coercive, mimetic and normative isomorphism. Individual survey items were drawn from literature on Institutional Isomorphism (DiMaggio & Powell, 1983; Scott & Meyer, 1982) and governance principles (Armstrong, 2004; Australian National Audit Office, 2014; Barrett, 2003; Edwards & Clough, 2005) as well as the Victorian government NMA guidance (Victorian Department of Health and Human Services, 2013). Research participant demographics were also collected to provide a basis for comparison between groups by helping to define the population under study and reduce the possibility of a sampling bias or error (American Psychological Association, 2010).

The survey was comprised of four sections.

Section One: Participant demographics

Section Two: The importance of research in public hospitals

Section Three: Isomorphic influences on site governance practice

- *Coercive influence*
- *Mimetic influence*
- *Normative influence*

Section Four: Free text fields

- *What systems, processes or initiatives have you encountered (or implemented) that assist research review or oversight?*
- *What systems, processes or initiatives have you encountered (or implemented) that assist research review or oversight?*
- *Would you like to make any other comments?*

(See Appendix C for a full explanation of survey development).

4.7.5 Phase Two: semi-structured interview

The second phase of the study was informed by the findings from Phase One and explored how leaders in the research sector anticipated the future direction of the NMA and research governance reform. Figure 4.2 was used as a basis for the semi-structured interview schedule.

Semi-structured interviews were used to ask three questions:

- What is your understanding of the National Mutual Acceptance (NMA) or national model of single ethical review of multi-site clinical trials?
- What do you see as the enabler/barriers to a national single ethical review/ streamlined process?
- What is the future of the NMA of single ethical review of multi-site trials?

4.8 Summary

Chapter Four presented and discussed the conceptual framework as a basis for both the quantitative data collection in Phase One and the qualitative data collection in Phase Two.

The initial step in developing the framework was to identify theoretical and practical bases to the model. The theoretical basis was Institutional Isomorphism and a "four pillar" model for analysing the global attractiveness of the clinical trial environment in Australia provided practical measures of research governance. The theoretical influences of coercive, mimetic and normative pressures were paired with the pillars of timeliness, quality, value and capacity in a crossover model. In this model coercive pressures drove government endorsement of the legitimacy of the NMA, expressed as performance timeliness; mimetic pressures drove public endorsement (value and capacity) and normative drove professional endorsement (quality).

This crossover led to the creation of propositions that align with key isomorphic mechanisms, in order to account for dynamic influences on organisation behaviours in the governance of research. Linking theory and praxis through concepts theories is further developed in the following chapter where the methodology and the definition of variables are presented.

Chapter Five builds on the conceptual model to present the research design and methodology used to undertake this research. The research design utilises both quantitative and qualitative research methods in a mixed methods approach.

CHAPTER FIVE: METHODOLOGY

5.1 Introduction

Chapter Five presents the research design and methodology used to undertake this research. The research design represents both an interpretivist and positivist paradigm, utilising both quantitative and qualitative research methods in a mixed methods approach. This design was adopted to explore the research questions and hypotheses posed by the study and to achieve the aims and objectives outlined in the introduction and Chapter Four. A mixed methods approach was employed to develop insights into the study topic that could not be fully understood using only a quantitative or a qualitative method.

The structure of this chapter is as follows. Section 5.2 describes mixed methods design. Section 5.3 outlines the mixed methods design used in this study. Section 5.4 describes the Phase One survey and Section 5.5 depicts the Phase Two interview. Section 5.6 explains how triangulation was used in this study to combine the findings from both phases. Section 5.7 provides the ethics approval for the study. Section 5.8 identifies some of the limitations of the study design, which are further discussed in Chapter Nine. The chapter was summarised in Section 5.9.

5.2 Mixed methods design

This was an exploratory study to investigate the variables that influence decision-making in regard to the NMA of single ethical review of multi-site clinical trials. It was a field study as it was undertaken in the natural environment, with minimal researcher interference. The unit of analysis for this project was the Victorian public healthcare sector. Data for analysis was collected through an anonymous survey and semi-structured interviews. A sequential, mixed methods model of research design was used in this study. To create robust research findings, triangulation was applied to contrast and compare the findings of the separate datasets.

5.2.1 Mixed methods research design

Mixed methods research is usually considered when neither the quantitative approach nor the qualitative approach, by itself, is adequate to develop a complete understanding about a research problem or question (Venkatesh et al., 2013). Literature indicates that the more common reasons for use of mixed methods research include: to develop a more complete understanding of a problem; to compare, validate, or triangulate results; to provide illustrations of context for trends, or to examine processes/experiences along with outcomes (Plano Clark, 2010). Other authors argue that mixed methods research is a research design "with philosophical assumptions as well as methods of enquiry" (Creswell, 2011, p 271).

This study was designed to enable the phenomenon to be considered through both positivist and interpretivist paradigms, firstly though quantitative and then qualitative research methods. This approach was assumed in order to quantify current beliefs and then to explore how the leaders of this sector perceived the future of the NMA. There was also a need to synthesise the findings of the two approaches in order develop robust conclusions about how the National Mutual Acceptance (NMA) impacted on the research sector.

Mixed methods research may employ quantitative and qualitative research methods concurrently and independent of each other, or sequentially, so that findings from one approach may inform the other, in order to understand a phenomenon of interest (Venkatesh et al., 2013). Sequential design was adopted in the current project in order to confirm preliminary baseline data on current research governance practices before exploring perceptions of why specific practices had developed and possible future developments.

Traditionally, there are two methodological approaches to research. A positivist approach maintains that a single world view exists and that an explanation can be found and tested by scientific standards of verification. Alternatively, an interpretivist approach seeks to understand a subjective account shaped by a viewer's perceptions. This approach recognises that there may be multiple versions of the truth. These two perspectives and the seemingly discordant forms of analysis they imply, have

traditionally divided social scientists. Nevertheless, the field of mixed methods research, sometimes referred to as the "third methodological movement" (Teddlie & Tashakkori, 2011,p 285) offers a pragmatic alternative. Rather than focus on the philosophical basis to data collection, proponents of mixed research argue that the decision to conduct mixed methods research should centre on the research question, purpose, and context (Venkatesh et al., 2013).

5.2.2 Challenges to mixed method design

Mixed methods research is usually considered when neither the quantitative approach nor the qualitative approach, by itself, is adequate to develop a complete understanding about a research problem or question (Venkatesh et al., 2013). Literature indicates that the more common reasons for use of mixed methods research include: to develop a more complete understanding of a problem; to compare, validate, or triangulate results; to provide illustrations of context for trends, or to examine processes/experiences along with outcomes (Plano Clark, 2010). Mixed methods research is a research design "with philosophical assumptions as well as methods of enquiry" (Creswell, 2011, p 271 and the field of mixed methods research, is sometimes referred to as the "third methodological movement" (, p. 295Teddlie & Tashakkori, 2011)

However, combining methodologies has sometimes been seen as problematic because of the view that quantitative and qualitative belong to separate and incompatible paradigms. The two perspectives and the seemingly discordant forms of analysis they imply, have traditionally divided social scientists. Critics of mixing research methods argue that differences exist on matters of ontology, epistemology, data collection methods and methods of evaluation.

Difference in Ontology

The objective measurements of quantitative methods are perceived as more reliable and detached. Use of statistics provides a powerful mechanism to generalise a finding, reduce a complex problem to a limited number of variables and examine relationships between variables. Thus, in highly controlled circumstances, statistics can establish cause and effect. Unlike the deductive nature of quantitative research, qualitative enquiry is a form of social enquiry that focuses on the way people make sense of their

experiences and the world in which they live. There is no single qualitative research technique, rather it is an overarching term that covers an array of interpretive techniques (Holloway & Wheeler, 2010; Speziale & Carpenter, 2007). Therefore, mixing methods needs to address the different paradigms under which the data were collected as well as recognise that qualitative techniques differ.

Epistemology

Combining two methods in one study can require more time, work, effort, and resources than do studies that use only a single method. Implementation and analysis of both methods requires greater experience and skills in both quantitative and qualitative methods (Holloway & Wheeler, 2010). This was addressed in the current study by forming a research team that had members with quantitative and qualitative expertise and by the candidate training in both quantitative and qualitative research.

Data collection methods

One of the main design challenges is the order in which data is collected and how the first collection should influence the second. Qualitative research is primarily exploratory research, used to gain an understanding of underlying reasons, opinions, and motivations. If undertaken first, it may provide insights into the issues being studied or assist in the development of ideas or hypotheses for potential quantitative research. Quantitative Research quantifies the issue understudy by way of generating numerical data or data that can be transformed into usable statistics. It is used to quantify attitudes, opinions, behaviours, and other defined variables to formulate facts and uncover patterns in research. Quantitative approaches involve large sample sizes which allows results to be generalised. The rationale for using this approach first is that the quantitative data and their subsequent analysis provide a general understanding of the research problem. The qualitative data and their analysis refine and explain those statistical results by exploring participants' views in more depth (Creswell & Plano Clark, 2006).

Methods of evaluation

When mixing research methods, researchers need to consider managing weight of each data set; whether equal weight is given to each data type or if one set supports the other. Creswell and Plano Clark (2006), for example, present numerous combinations of

mixing methods where data collection and analysis may be concurrent or sequential. The research model is also important if, for example, there is disagreement between quantitative and qualitative results.

5.3 Research design

5.3.1 Study population

The target population of this study comprised of those personnel involved with the National Mutual Acceptance (NMA) in Victoria. Data collection was limited to Victoria because the differences in the regulatory framework provided a logical boundary and minimised possible distractions of other regulatory requirements.

The eligible population was further divided into those involved with submitting a multi-site clinical trial or research study for review (Applicant) and those public healthcare who ensured that submissions complied with the relevant standards and regulations (Regulators). The Applicant group comprised of researchers, research coordinators and research sponsors, including contract research organisations (CRO) which were involved as an Australian legal entity if an overseas commercial trial sponsor did not have an Australian legal presence. Research Regulators were those involved with ensuring the project conformed to all the requirements of the public healthcare agency. The exact numbers of personnel engaged in clinical research, either as an applicant or regulator, are not defined but can only be estimated.

As an indication of the numbers of personnel involved in multi-site research, the Victorian healthcare sector includes 13 major independent medical research institutes, 11 major teaching hospitals, nine universities and a range of clinical trial operators and CRO's (Victorian Department of Health, 2013c). It has been estimated that the state's broader life sciences sector employs more than 22,000 people; Victoria's life sciences companies directly employ 6,000 people, with an estimated 2,300 in research and development roles. Multinational corporations employ a further 4,200 (Department of Business and Innovation, 2012). Personnel from any of these entities may apply for a single HREC to review a multi-site trial or research project under the NMA. Additionally, personnel from outside Victoria could also apply to a Victorian HREC for consideration of a multi-site clinical trial or research project.

As an indication of number of personnel involved in research regulation of multi-site research reviewed through the NMA , the Victorian Department of Health and Human Services (DHHS) lists 18 public healthcare agencies where a research governance officer (RGO) is employed (Victorian Department of Health, 2015). The RGO is a designated role with a research administrative office who is involved in managing research proposals for site specific applications. The healthcare agencies licenced to use the dedicated IT system are formally aligned through an MOU with the DHHS to accept the outcome of a single ethical review. Seven of those agencies also housed accredited HRECs able to undertake ethics reviews on behalf of the NMA. In addition to the 18 agencies listed by the DHHS, other Victorian organisations that are not signatories to the MOU may choose to accept an HREC decision of a project reviewed through the NMA. Personnel involved in endorsing the involvement of an agency or agency service department were also considered eligible to participate in the study.

Phase Two involved interviewing multi-site research leaders, who were those personnel actively engaged in how multi-site research and single ethical review was practiced. This included personnel from managerial or executive roles who were involved with research governance decision-making in the course of their employment but it also included other involved in relevant professional groups concerned with the management of multi-site research.

5.3.2 Dates of data collection

Data were collected in two phases. Phase One data was collected between 17 August 2015 and 1 October 2015. Phase Two data was collected between 1 June 2016 and September 30 2016.

5.3.3 Stages of data collection

This section discusses the different data collection methods used in the study. The data was collected and managed in a series of sequential steps, in order to ensure that the prior stage lead into the next.

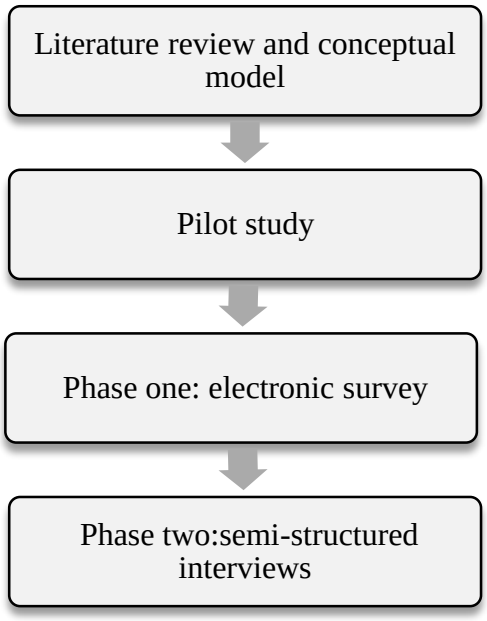

Figure 5.1 Sequence of data collection steps

5.3.4 Review of current literature.

The literature search, described in Chapter Two, informed the development of the conceptual framework. The dearth of information concerning the research governance practices of public healthcare agencies in relation to multi-site research combined with concerns from researchers about consistently overly bureaucratic and duplicative review processes suggested an opportunity to examine organisational processes of healthcare agencies through which group behaviours develop. Of the governance theories reviewed, the theory of Institutional Isomorphism (DiMaggio & Powell, 1983) provided a structure for examining pressures on organisational decision-making. This theory informed the development of the conceptual model in combination with a four pillar framework, identified from industry data, which provided objectives for analysis.

The approach to data collection was particularly influenced by experiences of public sector centralisation in the UK. Ashworth et al (2007) found that the impact of isomorphic pressures was stronger on organisational strategies and culture than on structures and processes. Franck et al. (2004) observed the likelihood on conflict between trying to meet local quality assurance needs while addressing the goals of a national model. Howarth et al. (2008) explored the effectiveness of a centralised research governance model in the UK through an electronic survey to explore researchers' experiences which was then followed by semi-structured interviews with

managers. The data collection methods used in this study reflected the approach by Howarth et al. (2008).

5.2.7.2 Quantitative and qualitative approaches. The two main types of research methods are quantitative and qualitative. Quantitative research aligns with the positivist paradigm, affording a formal, objective and deductive approach to problem solving. In contrast, qualitative research is aligned with the naturalistic paradigm and provides a more informal, subjective, inductive approach (Keele, 2012). The different qualities of the approaches are presented in Table 5.1.

Table 5.1: Comparisons of major assumptions of positivist and interpretivist paradigms

Positivist paradigms	Interpretivist paradigms
There is a single reality that can be measured	There are multiple realities that can be studied only holistically and cannot be predicated or controlled although some level of understanding can be achieved
The researcher and the research participant can remain independent of one another and not influence one another	The researcher and the research participant cannot remain separate or independent. They interact and influence one another
Findings of research can be generalised from the study population to the larger target population.	Findings cannot be generalised beyond the study sample. Knowledge gleaned from the study is in the form of working hypotheses
Cause and effect relationships can be tested	Cause and effect relationships cannot be tested since there are multiple realities that are continually changing, so it is not possible to distinguish cause from effects
Research can be conducted objectively and value free	Research is subjective and value bound (i.e. the researcher's own values)

Adapted from Quantitative versus qualitative research, or both? by R.Keele. 2012 in *Nursing Research and Evidence-Based Practice*. USA: Jones & Bartlett Learning, LLC.

The epistemological differences of quantitative and qualitative research paradigms are based on interpretations of reality. In qualitative research, reality is observable, empirical, measurable and subject to specific principles of reasoning. In this approach, science is seen as the way to identify the truth, and thus allowing prediction and control. In comparison, qualitative research is based on interpretivist paradigms, and is

positioned almost diametrically opposite the positivist paradigm. Qualitative enquiry is a form of social enquiry that focuses on the way people make sense of their experiences and the world in which they live. Rather than universal laws, qualitative enquiry recognises that there can be many versions of truth (Holloway & Wheeler, 2010; Speziale & Carpenter, 2007).

Although the quantitative and qualitative paradigms are not entirely dichotomous, the two differing approaches require different methodologies and data collection strategies (Holloway & Wheeler, 2010). The positivist approach was used to develop the Phase One survey, in order to provide a dataset of statements that could be cross tabulated against each other as well as individual demographics. This dataset was then used to inform the Phase Two interviews. Use of the interpretivist approach in the following semi-structured interviews was critical to fostering a dialogue between researcher and respondents that allowed for more informed and sophisticated understanding of the current impact and possible future directions of the NMA. The two data collections were then synthesised to produce a more robust finding.

5.3.5 Pilot study

A pilot study of the survey was conducted in order to evaluate the feasibility of undertaking the electronic survey and to determine if any adjustments of the design were required prior to release of the final version of the survey to the target population. There were 16 participants in the pilot: 9 health researchers, 1 ex-trial coordinator, 3 non health researchers and 3 non researchers. Despite the different backgrounds of the participants, there were no discernible differences in their evaluations.

The pilot participants reported that they were able to complete the survey within the target time of between 10 minutes to 20 minutes. They described the survey language as understandable and the instructions as clear. The layout of the form was considered appropriate.

Three issues were identified in the pilot study: an initial problem with redistribution was found to be a software setting; all pilot participants described the introduction as too long and that an ideal length for an introduction to a survey was considered less than a

screen; and concern was expressed that the term “public healthcare agency” was not familiar to potential survey respondents. It was suggested that the term be replaced by the word “hospital” in the survey.

The recommendations were accepted and the survey amended accordingly. The pilot data was discarded as the participation was based on the request to evaluate and not consistent with survey eligibility criteria.

5.4 Phase One: anonymous survey

5.4.1 Recruitment

Potential participants were invited to the study through direct emails and open invitations.

Direct email to Regulators

Direct email was sent to potential Regulator participants who had a publically available email address, either on their own website or listed in the contacts for reviewing HRECs and Research Governance Officers (RGOs) from the website of the Department of Health & Human Services (Victorian Department of Health and Human Services, 2016a) (Appendix B). Some offices supplied a generic email address and did not supply personal email addresses. In this eventuality, an electronic invitation and reminder was sent to the generic email address.

Direct email to Applicants

Email invitations were sent to select Applicants. However, Applicants were less likely to have publically available email contact so it was anticipated that contact with them would be made through the research offices or through research networks.

Open invitations

Emails were also sent to a contact from a commercial pharmaceutical sponsor, the research network Victorian Association of Research Nurses (VARN) and the Victorian Research Governance Network (VRGN) in anticipation that these recipients would be able to redistribute the invitation to their own connections. On 1 September 2015, the

ARCS “Jobs and News Bulletin”, an electronic newsletter, provided an invitation to participate in the survey and interviews (Appendix 4). ARCS Australia Ltd (previously the Association of Regulatory and Clinical Scientists) is a professional development association for therapeutic goods. It was anticipated that the ARCS bulletin would reach the broader community of those involved with clinical trials (Appendix B).

5.4.2 Sample

The Phase One survey eligibility criteria required that survey respondents were involved in multi-site trials in public healthcare in Victorian. It was anticipated that the main difference in opinion between potential respondents would be related to whether they were involved with applying for consideration of their research (Applicant) or involved in in research proposal reviewers (Regulator). Phase one recruitment strategies were electronic; invitations were issued through email and an electronic newsletter.

5.4.1.1 Applicant sample. Applicants were those involved with submitting a multi-site clinical trial or research study for review as described in Table 5.1. The group comprised of researchers and research coordinators as well as research sponsors and contract research organisation (CRO). While all of these personnel are involved in the application process, the researcher and trial coordinator are associated with the agency undertaking the trial or research but the sponsor and CRO personnel are generally external. The trial sponsor is responsible for overall conduct of the trial or research. For clinical trials, the type of sponsor will vary from trial to trial depending on the nature of the trial. For an international clinical trial, where the sponsor is not an Australian legal entity, a CRO is employed to act as the Australian sponsor for the trial. It was anticipated that perception might differ between those employed by the agency such as, researchers and trial coordinators, compared to those employed externally such as, clinical trial sponsors and CRO.

Table 5.1 Summary of the range of roles involved in the Applicant sample

Role	Definition
Coordinating principal investigator (CPI)	The individual who takes overall responsibility for the research project and submission of the multi-site project for ethical review on behalf of all the participating agencies. Also responsible for ongoing communication with the reviewing HREC , including advising all Principal Investigator (PI) teams at each site conducting the research of the HREC decisions
Principal investigator (PI)	The individual responsible for the conduct of the clinical trial at specific trial site
Trial Coordinator	Trial coordinator is responsible for conducting clinical trials using good clinical practice (GCP) under the auspices of a Coordinating principal investigator (CPI) or Principal Investigator (PI). This includes making ethics and governance applications
Sponsor	An individual, company, institution, or organisation who takes responsibility for the initiation, management, and/or financing of a clinical trial. Must be an Australian legal entity.
Contract Research Organisation (CRO)	An organisation contracted by another company to manage almost all aspects of a clinical trial, from site selection and participant enrolment through final regulatory approval. May act as the local commercial sponsor for legal purposes
Head of supporting department	Depending on the nature of the research, various service providers may be involved such as pharmacy or medical imaging

5.4.2.1 Regulator sample

The Regulator sample included public healthcare agency personnel involved with ensuring that a clinical trial conformed to all the requirements of the healthcare agency, including all the relevant legal and regulatory conditions (Table 5.2).

Table 5.2 Summary of the range of roles involved in the Regulator sample

Regulator Role	Definition
Authorising authority	The Chief Executive Officer (CEO) or delegate provides final decision on whether the trial or research project may be undertaken at that site.
Ethics administrator	Personnel who manage research ethics application process, including the distribution of ethics applications to ethics reviewers provide written confirmation of the ethics decision to the applicant
Head of supporting department	Depending on the nature of the research, various service providers may be involved such as pharmacy or medical imaging
Human Research Ethics Committee (HREC)	Accredited committees able to provide single ethical review decision. Victoria has seven accredited HRECs
Research Governance Officer (RGO)	Personnel who manage the site specific assessment of a research application. Liaises between researchers and organisation's authorising authority to ensure that the site authorisation process is timely and that legal compliance, financial management, accountability and risk management associated with research have been addressed.
Research Office	The office responsible for administrative governance of research: may include providing secretariat support and ensuring that research protocols are compliant with all relevant guidelines and legislation. Personnel may include research director, research manager, RGO and ethics administrators.

5.4.3 Probability sampling

Probability sampling is any method of sampling involving some form of random selection. All personnel involved with Victorian multi-site clinical trials reviewed through the NMA of single ethical review were eligible to participate. The sample goal was 200, comprised equally of Applicants and Regulators.

5.4.4 Advantages and disadvantages of electronic surveys

Advocates of electronic surveys assert that the internet offers many advantages over traditional paper survey methods, including substantial data collection efficiencies, cost advantages, and wider dissemination of internet access among diverse groups (Roster, Rogers, & Albaum, 2004). Use of online surveys is best suited for situations such as: coverage of a wide geographic area or a large sample is desired, interviewer interaction with respondents is not necessary and/or desirable; and timeliness is vital (Evans &

Mathur, 2005). Evans and Mathur also identified possible weaknesses of online surveys. Table 5.3 outlines how these were addressed in the survey.

Table 5.3 Addressing the potential weaknesses of online surveys

	Potential weakness	**Solutions addressed in the study**
Sample	Lack of representativeness. Sample selection e.g. skewed attributes of internet population Issues of reaching the target population	Aim to capture large sample. Use of different approaches e.g. direct email and published invitation to participate
Technical delivery	Level of respondent skill required Perception as junk mail Variations in user technology	Opt in survey: brief email with URL link Ensure survey can be read on multiple devices
Survey	Unclear instruction Timeliness, difficulty or relevance Impersonal Privacy/ security concern Rigidity Low response rate (<60%)	Simple instructions Use of survey IT through which anonymity can be assured Offer "free text" options to increase flexibility Email reminders

In particular, the current design noted the possibility of the unsolicited email invitation to participate in the survey to be discarded and potential participant burden of having to complete the survey. While the possible limitations were recognised, the decision to employ an electronic survey in Phase One was based on the requirement for a broad range of respondents, many of whom would not have a publically available email address.

5.4.5 Electronic survey instrument

The survey was hyperlinked to the email inviting participation, and recipients of the invitation were encouraged to extend the invitation to their own networks. Additionally, in keeping with current literature, the survey was intended to be relevant and of interest to the targeted respondent because it involved their work area (Evans & Mathur, 2005) and expected to take less than 20 minutes because the amount of time and effort needed to complete a survey impacts on response rate (Brown , Culkin , & Fletcher 2001).

The survey was divided into five areas: invitation to participate, about yourself (demographic data); the importance of research in public hospitals; influences on site

governance practice and free text of the respondent's experiences (Appendix C). The survey responses categories are presented in Appendix D.

Section One: About yourself. Section One used multiple choice to collect demographic data: age, education, gender, role, job status, number of years worked in the current role and location.

Section Two: The importance of research in public hospitals. Section Two explored respondents' perception of the importance of research being regarded as a core healthcare agency activity. They were asked to rank a series of statements about the how research should be integrated into the agency management framework before being asked to rank their perception of how hospitals regarded research in reality.

The section employed 5 point Likert scales (very important to very unimportant) to solicit response to the main question then 5 point Likert scales (strongly agree to strongly disagree) to elicit response to the confirming questions. The Likert scales were used to capture the intensity of respondents' feelings for a given item in a consistent manner. [10]

Section three: Influences on site governance practice. Section Three addressed perceived impact of the NMA as providing coercive, mimetic and normative isomorphic influences on site practices. In keeping with Section Two, 5 point Likert scales were employed to gauge the respondent's reaction to the main question and then rank a series of supporting statements.

The first part addressed the NMA as a coercive influence. Respondents were asked to indicate the importance of the NMA to regulation of research in hospitals and then to rank a series of statements about compliance to the NMA before ranking the influence of the NMA impact in reality.

The second part addressed the NMA providing a mimetic influence. The initial statement asked about the importance of the NMA providing certainty by setting a

[10] The 5 point Likert scales were reduced to 3 point Likert scales for analysis

standard time by which projects should be approved. Respondents were then asked to rank statements about managerial opportunities to compare with others, before ranking the degree to which the NMA does provide certainty.

The third part of this section explored the NMA as providing a normative influence. The concept of professional standards in research governance was used as a proxy for the NMA, as Institutional Isomorphic literature suggest normative forces provides an inter-organisational influence. Respondents were asked to rank statements about research governance practices before ranking the degree to which research governance standards exist.

Section four: Your experience of research governance practices. Respondents were invited to comment on site specific assessment in Section Four through prompts asking what enabled and what detracted from the research review process.

5.4.6 Data collection procedure

The anonymous, electronic survey opened on the 17 August 2015 and closed on the 1 October 2015. Invitations to participate in the study were undertaken in three ways. A direct invitation, including a hyperlink to the survey, was issued to those potential respondents with a publically available email addresses. They were also encouraged to invite others to complete the survey. One reminder email was sent to the email recipients two weeks later. On 1 September 2015, the ARCS "Jobs and News Bulletin", an electronic newsletter, published an invitation to participate in the survey and interviews. The advertisement was hyperlinked to the survey.

A written consent to participate was not required. It was deemed that a respondent's consent to participate is implied through their completion of the survey.

5.4.7 Data analysis methods

In testing the hypotheses proposed by this study and to achieve the study's objectives, methods of data analysis included descriptive and inferential statistics. Demographic data collected as discrete and numerical. Data collected from survey sections two and three involved Likert scales, which allowed respondents to rank their responses. In

order to apply statistical analysis, an assumption was made that the variables are considered as interval data and equally spaced.

The Statistical Package for the Social Sciences (SPSS) was used to analyse quantitative survey data. Univariate Analysis was used to summarise the responses to each question, such as distribution; central tendency and dispersion. Cross-tabulations were performed for each question along with Pearson's Chi-square (x2) testing for independence. Pearson's Chi-square, a statistical test to evaluate the likelihood of any observed difference between the sets arising by chance, was then applied to test the hypotheses and explain the interaction between the variables. Findings from the data analysis are discussed further in Chapter Eight.

5.7.6.1 Descriptive analysis. Descriptive statistics were used in this study to summarise the distribution of responses to each survey item in Sections One to Three.

5.7.6.2 Inferential statistics. Inferential statistics were used to make judgments of the probability that an observed difference between groups might have happened by chance. Cross-tabulations were performed for each question along with Pearson's Chi-square (x^2) testing for independence or chance. Pearson's Chi-square was then applied to test the hypotheses and explain the interaction between the variables.

Hypotheses were considered supported using descriptive statistics if there were more responses in the direction of the hypotheses. Hypotheses that were evaluated using Pearson's Chi Square were considered supported if a significant relationship between variables was identified. Significance was determined at .05 (5%), meaning that a Chi-square determination of or less than .05 ($p=\leq .05$) was considered a significant indication that the data distribution was not by chance and there was an association between the variables.

5.7.6.3 Factor analysis. Factor analysis is a method of data reduction used to describe variability among observed, correlated variables with regard to identifying a reduced number of latent variables called factors (Yong & Pearce, 2013). Factor loading refers to the extracted values of each item. The higher the absolute value of the loading, the

more the factor contributes to the variable. Those with a factor loading of less than.600 were discarded from further analysis.

In the current study, factor analysis was performed to identify the correlation among the variables in all four constructs of the study. It was used as the confirmatory measure of the variables in the each construct, namely: the importance of research in public healthcare agencies and the impact of the NMA as a coercive influence, as a mimetic influence and as a normative influence. Factor analysis provided a mechanism through which the reliability of the constructs and the validity of the variables in each construct was explored.

Although literature suggests that isomorphic influences are interdependent (Mizruchi & Fein, 1999), each survey construct was considered a distinct entity for the purposes of determining the validity of the variables. Four separate factor analysis were undertaken: research importance, coercion, mimetic and normative influences. Smaller sample sizes are considered appropriate as long as "communalities are high, the number of expected factors is relatively small, and model error is low (a condition which often goes hand-in-hand with high communalities)" (Preacher & MacCallum, 2002, p. 160). A factor of 1 was chosen for each analysis and no rotation was used.

5.5 Phase Two: semi-structured interview

5.5.1 Sample

Phase Two involved interviewing multi-site research leaders, who were those actively involved in developing awareness of single ethical review, either through their employment or as part of a professional association.

5.5.2 Purposeful sampling

The second phase was designed to capture data from multi-site research "leaders" about why variations in site authorisation occur and how they perceived the future of the NMA and research governance. The majority of the leaders volunteered from Phase One to be interviewed. Two were invited on the basis of a recommendation.

The Phase Two involved purposive sampling. This approach is widely used in qualitative studies for the identification and selection of those participants who are information-rich in the phenomenon of interest (Creswell & Plano Clark, 2006; Palinkas et al., 2015). Purposeful selection of eligible participants is based on the judgement of the researcher (Holloway & Wheeler, 2010), as is the sample size required. The guiding principle for sample size should be the concept of saturation, which is when no new substantive information is acquired (Palinkas et al., 2015).

Despite its wide use, literature notes that numerous challenges apply to purposeful sampling strategy. It can be prone to researcher bias, meaning that, for example, the findings may not be generalizable to a broader population (Holloway & Wheeler, 2010; Palinkas et al., 2015). In this study, the eligibility criteria for the term "leader" was intentionally imprecise, in the expectation that the interviews would be an iterative process, where the outcome of one interview helped to determine a subsequent interest in the next. This belief was substantiated when different personnel described the same situation from different viewpoints.

5.5.3 Advantages and disadvantages of interviews

Literature suggests that semi-structured interviewing is best used when only one interview is being used to collect data (Bernard, 1988). It is based on the use of an interview guide, a written list of questions or topics to ensure the collection of comparable qualitative data between interviews. Semi-structured interviews are characterised by open-ended questions and the use of "probing" to encourage the interview to expand on their responses (Palinkas et al., 2015). Probing allows the interviewer discretion to follow leads and provide some latitude to interviewees to provide new ways of seeing and understanding of the topic.

The ability for qualitative data to provide a rich, detailed picture of why people act in certain ways, and their perceptions about the world around them also provides limitations of the method. Common limitation associated with qualitative data include:

- Risk of collecting too much information or the collection of more 'noise' than information because the aim of qualitative analysis is a complete, detailed description.

- Usually fewer people studied: collection of qualitative data is generally more time consuming that quantitative data collection and therefore unless time, staff and budget allows it is generally necessary to include a smaller sample size.
- Less easy to generalise: the nature of qualitative data and because qualitative studies usually involve fewer participants, it is not possible to generalise results to that of the population. Usually exact numbers are reported rather than percentages.
- Difficult to make systematic comparisons: for example, if people give widely differing responses that are highly subjective.
- Dependent on skills of the researcher: particularly in the case of conducting interviews, focus groups and observation (Atieno, 2009).

5.5.4 Reflexivity

The impact of the researcher has become increasingly salient. Concerns have been raised that researcher interaction with those being researched inevitably influence research processes and outcomes. This is particularly pertinent for qualitative research projects, because qualitative methods are less structured than quantitative methods and involve close interaction with research participants in exploring their respective research fields. Reflexivity is the "critical reflection on what has been thought and done in a research qualitative project" (Holloway & Wheeler, 2010, p. 8), because it locates the researcher in the research project. It has also been argued that reflexivity is an active, ongoing process that saturates every stage of the research, rather than a single activity. In this sense, a researcher would be alert not only to issues related to knowledge creation but also ethical issues in research (Guillemin & Gillam, 2004).

The researcher maintained awareness through introspection of her own experiences and insights. Member checking was used to truly reflect what the participant meant. During the interviews, the researcher restated or summarized what the participant had said during the interview to determine accuracy. The participants were also offered the opportunity to review the interview transcript. These findings and research insights were compared with current literature. In this sense, reflexivity provided an ongoing sensitizing tenet throughout the whole study, which is supportive of previous literature (Guillemin & Gillam, 2004; Watt, 2007).

5.5.5 The semi-structured interview

Semi-structured, in-depth interviews were used to explore participants' experiences multi-site clinical trials reviewed through the NMA. Ethical approval required that a written consent was required to participate in the interviews. Participant consent is established before the interview commenced. The participant information and consent form explained the interview process. Once the potential participant agreed to an interview, the interview time and venue were arranged. Interviews were audio-taped, with the interviewee granting permission for the interview to be transcribed. The transcription was then provided to the participant, if they wished, for verification prior analysis.

Each interview, with one exception, was audio-taped and transcribed with the participant's consent. For the interviewee who did not want to be audiotaped, written notes were taken and transcribed. Transcriptions were then made available to the interviews for their validation of the truthfulness of the data. On return from the interviewee, the transcriptions were then thematically analysed.

The semi-structured interviews were based on an interview guide which consisted of two levels of questions: main theme of each section and probing or follow-up questions (Appendix L). Participants were then encouraged to speak freely about their perceptions and experiences. The interview addressed the following.

1. Question one invited participants to describe their understanding of the National Mutual Acceptance (NMA) or the national model of streamlined research review. Participants were encouraged to reflect on their understanding of the current process and on their expectation. If required, a probing question about the extent to which their vision been achieved was used.

2. Question two sought to assess the participant's view on the enablers or barriers to the successful implementation of the NMA as a national single ethical review streamlined process.

4. Question three sought details about the future of the NMA. This was followed up by probing questions about the extent to which the NMA provided isomorphic pressures on agencies to behave in certain ways. The first probe asked about the strength of the NMA as a coercive influence on the way bureaucratic processes around research review were conducted. In particular, participants were asked to identify strengths and weakness NMA and how that could be addressed in the future. The second probe explored the NMA as a mimetic pressure. It asked participants to comment on whether regulators should look to their peers for guidance on research governance. The third probe considered the normative influence of the NMA. Participants were asked to reflect on any standardised credentialing or education requirement relevant to employment in research governance.

In addition, not all of those invited to participate in interviews agreed. This suggests a possibility that the interviews also might lead to overrepresentation of particular opinion views. Furthermore, Phase Two data collection was limited by the overall availability of research leaders who were only able to allocate time for one interview. Potentially, further discussion could have expanded on the issues raised in the interview.

5.5.6 Data analysis methods

Qualitative data was included in this study to develop in-depth description of how the interviewees were experiencing their involvement with single ethical review of multi-site research. Interview recordings were transcribed into written form to enable them to be studied in detail and coded. Coding and categorising is an integral component of qualitative research. Data are transformed and reduced to build categories, which are then labelled. Interrelating concepts are then refined into themes (Holloway & Wheeler, 2010). These methods allowed theme development to reflect a synergistic combination of the participants' words and the analyst's interpretation. Interrelationships were then mapped and similar themes grouped to establish higher level concepts.

In qualitative research, thematic analysis is a popular method for identifying, analysing and reporting patterns (themes) within data (Braun & Clarke, 2006). Through thematic analysis, narrative data can be reduced to the core experience that reflects the narrator's

account, even if the account has not been presented in an ordered or sequential manner (Holloway & Wheeler, 2010).

There are six phases of thematic analysis:

1) Familiarisation with the data.

2) Coding which is an analytic mechanism through which the narrative is reduced and labelled.

3) Theme identification where coherent and meaningful patterns in the data are constructed in accordance with the research questions.

4) Reviewing and checking the themes involves the researcher reflecting on the nature of each individual theme, and the relationship between them.

5) Defining themes and contributing sub-themes requires the researcher to identify the "essence" of each theme.

6) Writing up, an integral element of the analytic process involves weaving together the analytic narrative and (vivid) data extracts to provide a coherent narrative about the data, which is contextualised in relation to existing literature (Braun & Clarke, 2006; Braun & Clarke, 2013).

5.6 Triangulation

5.6.1 Definition.

Based on the laws of trigonometry, triangulation is a method used to determine the location of a fixed point. Triangulation was commonly associated with maritime navigation where it was used to track a vessel's position (UNAIDS, 2010). In the social sciences , triangulation is "the process in which the phenomenon or topic under study is examined from different perspectives" (Holloway & Wheeler, 2010, p. 308). It is a popular method in qualitative research to cross-check multiple data sources to evaluate the extent to which all evidence converges.

Triangulation is also applied to the process used to corroborate and integrate findings from both qualitative and quantitative studies in a shared domain of empirical research. The focus of this process is integrations of data, or the results to summarise what is known about a target phenomenon and, thereby, to direct both practice and future research. The key characteristic of mixed methods triangulation is the combination of

quantitative and qualitative methods of data collection (concurrent or sequential) and a process of synthesis through which analysis is undertaken within a single research inquiry.

5.6.2 Strengths and weaknesses in triangulation

Literature suggests that using method triangulation in mixed methods research provides far richer findings than reliance on a single method (Creswell & Plano Clark, 2006; Venkatesh et al., 2013). Through methods triangulation, weaknesses in one dataset can be compensated for by the strengths of other data, thereby increasing the strength of the conclusions about findings and to reduce the risk of false interpretations (Holloway & Wheeler, 2010). The core strength of methods triangulation is its potential to uncover meaningful information that may have remained undiscovered with the use of a single approach.

Mixed methods triangulation has several weaknesses, including the challenges of comparing the findings of two different approaches and possible differences in the quality of the different methods (Venkatesh et al., 2013). It cannot compensate for inaccuracies of data in one or both of the data collections.

5.6.3 Triangulation of the current study

The study employed a non-experimental research design, which rests on observation and interpretation but is weak in assessing cause and effect. Triangulation was included in the research design to corroborate the findings of the different data collections and to provide a greater authority than a single approach.

If only quantitative research methods had been utilised in this study, it may have led to ambiguity and limitation concerning the impact of NMA on healthcare governance practices. It would also have been impractical to explore possible futures. Qualitative data was used to undertake an in-depth investigation of possible futures for the NMA. Qualitative data collection, however, is heavily dependent on the individual skills of the researcher and more easily influenced by the researcher's personal biases and idiosyncrasies. It is more difficult to demonstrate rigour in qualitative research (Holloway & Wheeler, 2010). The triangulation of these approaches, and other

secondary sources where relevant, substantiated the findings and provided a more robust platform through which inferences could be made.

Creswell and Plano Clark (2006) suggested four criteria in developing a mixed methods study that used triangulation to synthesis the research findings. These are implementation, priority, integration, and theoretical perspective and were applied in this study as follows. The study was implemented using quantitative data then qualitative. Quantitative data was used to quantify the impact of factors identified in literature as relevant to how isomorphism might occur and to determine any causal relationships. Qualitative data were used to explore causality further. Integration extended the scope and depth of understanding of how the NMA has influenced healthcare agencies and to identify the likely future impact. The study design, in respect to which method took priority in influencing decisions if findings from different methods do not agree, suggested that neither data had primacy. While the survey data scoped out the issues and the relationships, the interview data explored why events were occurring. Prioritising neither method meant that the two data collections were collected and analysed separately before any synthesis was undertaken. Consequently the convergence model formed the basis to the triangulation design (Creswell & Plano Clark, 2006). The convergence model is provided in Figure 5.2.

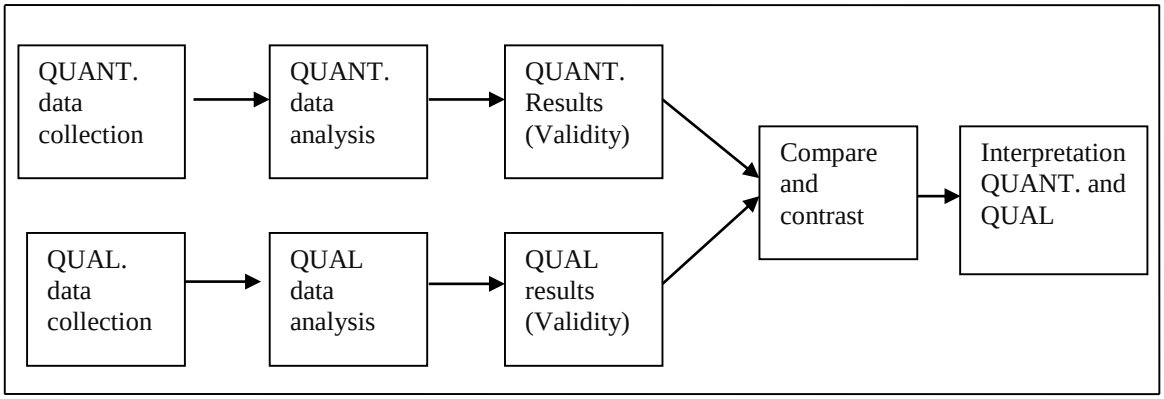

Figure 5.2: Triangulation design using a convergence model

Reprinted from Designing and Conducting Mixed Methods Research by J.W. Creswell, J. W., & V.L. Plano Clark, V. L. 2006, p.63. Lincoln, USA, SAGE Publications, Inc.

Data from the different methods were integrated following separate data analysis. Institutional isomorphism (DiMaggio & Powell, 1983) provided the theoretical perspective of the data collection from both phases. Mixed methods synthesis was conducted in accordance with the convergent validation proposed by Venkatesh, Brown and Bala (2013).

Criticism of the convergent validation model include that the triangulation logic must negotiate the fact that the same thing cannot be precisely measured twice (Denzin, 2009) and that mixing methods for the purpose of seeing if they agree is not unproblematic (Fielding, 2012).

In the current study, validation was used to corroborate the findings from the separate phases in relation to how the impact of the NMA was current perceived. The implication of this corroboration was that the participants' expectations of the future of the NMA would also be representative of a broader population. The comparison of the two datasets was based on Venkatesh et al. (2013) who argued that the concept of validity can be applied to both quantitative and qualitative data collections.

5.6.4 Validity

Within the quantitative or positivist perspective, validity and reliability are common tools of validation. Validity indicates the credibility or believability of the research and reliability refers to whether repeating the study would yield the same results. No such single or unitary concept of validation exists for qualitative research. However, Venkatesh et al. (2013) argue that in the context of a qualitative study, definitions of validity relate to the extent to which data are plausible, credible, and trustworthy, and thus can be defended when challenged. In keeping with this argument, the term validity is used at as the main concept of data validation in the current study. The study does not lend itself to measure of reliability because of the difficulty in reproducing exactly the same circumstances.

In quantitative research, the measures of validity are design, analytical and inferential validity. Design validity centres on how cause and effect are established, measurement validity is indicated by content and construct validity and inferential refers to the

conclusions that can be drawn from the use of statistics. In comparison, the measure of validity in qualitative research are: design validity, through description, credibility and transferability; analytical validity, which is based on the integrity of the theoretical foundations of the study, and inferential validity, which related the overall quality of interpretation and inferences. These are presented in Table 5.4.

Table 5.4 Examples of validity criteria in quantitative and qualitative research

Quantitative Research	**Qualitative Research**
Design validity	**Design validity**
Internal validity describes the extent to which an observed covariation between independent and dependent variables	*Credibility or trustworthiness* corresponds to the notion of internal validity in that the results of qualitative research are credible or believable from the perspective of the participants.
External validity: refers to the inference about whether the cause-effect relationship holds in other settings	*Transferability*: The degree to which the results of qualitative research can be generalized or transferred to other contexts or settings
Measurement Validity	**Analytical Validity**
Measurement validity involves both Reliability and Construct Validity. *Reliability* means repeatability or consistency and produces the same result over and over again and *Construct validity* defines the degree to which a test measures what it claims, or purports, to be measuring	Consideration of analytical validity also involve different facets. *Theoretical validity* defines the extent to which the theoretical explanation fits the data and, therefore, is credible and defensible. *Dependability* expresses the stability of data over time and over conditions, emphasising the need to describe specific setting changes that affected the way the researcher approached the study. *Consistency* refers to the process of verifying the steps of qualitative research and *Plausibility* is concerned with determining whether the findings of the study fit the data from which they are derived
Inferential Validity	**Inferential Validity**
Inferential Validity or objectivity refers to the validity of the statistical conclusion and the degree to which inferences about the correlation between independent and dependent variables are correct or reasonable	In comparison, in qualitative research Inferential Validity refers to the degree to which the results could be confirmed or corroborated by others.

Adapted from "Bridging the qualitative–quantitative divide: guidelines for conducting mixed methods research in information" by V. Venkatesh,, S.A. Brown & H. Bala,2013. *MIS Quarterly, 37*(1), 21-54

5.6.5 Phase One quantitative data

Phase One data was analysed through design, measurement and Inferential Validity. Design validity was demonstrated through use of cross -tabulation and Chi Square to investigate the likelihood the differences between the data sets occurring by chance. Factor analysis was the tool used to ensure the robustness of the data collection tool, the reliability of the constructs and the validity of the variables in each construct. Measurement validity involved model development from the theoretical and practical basis, so that the impact of the NMA providing drivers of legitimacy could be measured. Inferential Validity described inferences about any association between independent and dependent variables and thus the conclusions drawn from the data.

5.6.6 Phase Two qualitative data

Phase Two data was analysed using design, analytical and inferential validity. Design Validity of the qualitative data was aligned with use of coding and data reduction to create trustworthy findings. Analytical Validity was demonstrated through the structural consistency of the data collection. The semi-structured interview used an interview template, a pre-determined set of open questions, which was constructed on the same theoretical and conceptual models as the Phase One data collection. All interviews were audiotaped, transcribed and checked by the interviewees prior to thematic analysis. Themes were developed through systematised decisions which involved combining similar any similar topics. Thematic analysis was based on two or more participant statements and the themes were supported by relevant quotes. Inferential Validity referred to the degree to which the themes were supported. Use of the validity measures meant that inferences from both research paradigms could be effectively integrated into a theoretically consistent meta-inference.

5.7 Ethics approval

The *National Statement on Ethical Conduct in Human Research or National Statement* or National Statement (The National Health and Medical Research Council et al., 2007) states that research with humans may only be conducted with ethical approval. Accordingly, approval to conduct the human research elements of the study was gained from the Human Research Ethics Committee, Victoria University on 17 February 2015. A copy of the approval email is appended to this thesis (Appendix A).

The National Statement outlines four principles of ethical conduct that apply to all human research: research merit and integrity, justice, beneficence and respect. As this project is based on data collected from specific areas of the population, ethical consideration focussed particularly on the participants' autonomy in making the decision to participate or not in the study, having concern for their well-being and avoiding harm.

5.7.1 Privacy and confidentiality

The National Statement advises that "researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities" (The National Health and Medical Research Council et al., 2007, p. 11). Privacy refers to the concept of protection of a research participant's identity. Confidentiality refers to the treatment of information disclosed by a participant, with the expectation that it will not be divulged to others. While confidentiality is an ethical duty, privacy is a right rooted in common law. Several measures were used to maintain the privacy and confidentiality of the participants.

Interview transcripts were de-identified and pseudonyms used for any identifiers such as people or organisations. During the study, data was securely stored in a locked filing cabinet and a password protected computer which was accessible only to the author. At the completion of the project, the data will be retained for five years before being destroyed.

5.7.2 Phase One consent

Written consent was not required for the anonymous online survey. Those who wished to participate accessed the survey through on online system that did not record their identification. It was assumed that those who completed the survey were, in effect, freely consenting to participate and they had sufficient information about the study and the confidentiality of their responses to make that decision. The survey introduction also included advice on data confidentiality and guidance on who to contact for further information.

5.7.3 Phase Two consent

Written consent was required for those who agreed to participate in an interview (Appendix J and K). Firstly the participant information explained what was expected of the participant and the data management processes in detail. Permission was sought for taping the interview, a copy of the participant's interview transcription was made available to them shortly after the interview and before analysis to allow any corrections to be made. In the transcription all identifiers, including those of the participant, were replaced with a false name, in order to prevent identification.

In terms of ongoing confidentiality, the hard copy, paper documents relating to the participants were kept in locked filing cabinets in a locked room in the Department of Law and Justice. Transcriptions and other study data were stored as password protected files on the University server.

5.8 Potential study limitations

Study design included recognition of any in the research approach. It was noted that, firstly, restrictions of the study scope was restricted to Victorian public healthcare agencies, would constrain the generalisability of the finding. The decision to limit the study to Victoria was made because of concerns that inter-jurisdictional legislative and regulatory variations (National Health and Medical Research Council, 2014c) could potentially confound the study findings of the impact of the NMA.

In addition to issues associated with specific methodology, discussed in Sections 5.4 and 5.5 of this chapter, it was also noted that the difficulty of distinguishing between

different isomorphic influences may potentially capture more than one isomorphic pressure (Mizruchi & Fein 1999). Thus, the survey items asked about very specific issues. The study design addressed the potential limitations of the individual data collections through a mixed methods approach with triangulation which allowed the consolidation of the separate findings. As the intent was to capture user's perception of the NMA in both current and future context, these limitations were accepted and data collection proceeded.

5.9 Summary

Chapter Five built on the conceptual model, presented in the previous chapter, to detail the methodology used in the study. Because the study involved exploration of present and future impact of the NMA on research governance practices, there was an opportunity to include both quantitative and qualitative data in a mixed methods research design.

The mixed methods approach first collected quantitative data and then expanded the findings though qualitative semi-structured interviews. The intent of this data collection was to gather perspectives of both those involved with submitting a multi-site clinical trial or research study for review (Applicant) and those public healthcare personnel who ensured that submissions complied with the relevant standards and regulations (Regulators). Data sets were analysed separately and triangulated. Triangulation of the data was undertaken to corroborate and integrate findings from both qualitative and quantitative studies in a shared domain of empirical research. This was a critical aspect of the research design. Each dataset corroborated the findings of the other, which gave weight to the speculations about the future in Phase Two. The chapter also describes the population of the study, methods and sources of data collection, and statistical analysis used to test the propositions of the study. The ethical considerations, including how privacy, confidentially and participant consent, were managed was also addressed.

Chapter Six applies the methods discussed in this chapter to describe Phase one data collection in detail.

CHAPTER SIX: PHASE ONE SURVEY RESULTS

6.1 Introduction

This chapter presents results relating to the survey undertaken in Phase One of the study. The focus of the survey was to determine how the impact of the National Mutual Acceptance (NMA) on Victorian public healthcare agencies was perceived by those working in associated roles. Phase One data was collected through an anonymous electronic survey.

The Chapter is presented as follows. Section 6.2 and 6.3 describe the survey sample and the frequency distribution of the survey responses. Section 6.4 outlines the scoring of the data, whereas Sections 6.5 and 6.6 present the results of factor analysis and regression. Section 6.7 discusses how the hypotheses were addressed. An analysis of the qualitative responses from the survey is shown in Section 6.8. Section 6.9 concludes the chapter.

6.1.1 Recruitment

Potential participants were invited to the study through direct emails and open invitations. Table 6.1 lists the invitations and reminders that were sent directly from the researcher. A total of fifty eight original invitations and forty nine reminder emails were sent. Reminders were not sent to the sponsor, researchers, VARN, ARCS or VGN addresses as these recipients had redistributed their invitation via their own electronic means, such as newsletters.

Table 6.1: Emailed invitations to participate in the survey

Table 6.1: Emailed invitations to participate in the survey

	Email 1	Email 2 (Reminder)
Direct invitations		
Research Director	4	4
Research Office Managers	11	11
HREC administrators	7	7
RGOs	18	18
Research Office generic email	9	9
Sponsors	1	-
Researchers	5	-
Open invitation		
VARN, ARCS, VRGN	3	-
TOTAL	58	49

There were 150 responses, one of which was discarded because it was incomplete, leaving 149 as the final number. Of those 149, 24 surveys had one or more fields missing.

6.2 Survey sample

6.2.1 Sample size

Where the population size is unknown, a minimum sample size can be estimated through the formula: $n = z^2 (p)(1-p)/ c^2$, where z = standard normal deviation, p = percentage picking a choice or response and c = confidence interval. The smaller sample size required a lower confidence level, and a greater confidence interval. Thus the formula was revised to z = 90% confidence level (z=1.645), p = .05 and c= .067. Based on this formula, the minimal sample size was 149.7884. This was considered acceptable as other studies within this field (Ashworth et al., 2007; Howarth et al., 2008) used similar sized samples.

6.2.2 Description of the sample

Table 6.2 presents the respondent demographics. The most common respondents identified as Applicants and were: female, aged 49 or under, tertiary educated and had worked in their current role between over 6 years.

Table 6.2: Summary of respondents' demographics

Variables	Response proportion by category		Total Responses	
	%	Freq	%	Freq
Age			100	149
≤50	77	115		149
≥51	23	34		
Education			100	149
Post Grad	32	48		
Bachelor	58	87		
Pre Tertiary	9	14		
Gender			100	149
Male	25	37		
Female	75	112		
Role			100	149
Applicant	61	91		
Regulator	39	58		
Level			100	149
Management	36	54		
Non-Management	64	95		
Years			100	149
≤5	44	65		
≥6	56	84		

There were 149 responses to the survey that were accepted as valid. Of those, 91 identified as Applicants and 58 identified as Regulators.

6.2.3 Comparison of the respondent means

Survey respondent demographics are presented on the basis of the respondent's role: Applicant or Regulator. Of the 149 responses, 91 were from Applicants and 58 were from Regulators. (Table 6.3)

Table 6.3: Frequency and distribution of survey respondents' Role

	Frequency	Percent	Valid Percent	Cumulative Percent
Applicant	91	61.1	60.8	60.8
Regulator	58	38.9	39.2	100.0
Total	149	100.0	100.0	

Because of the differences in size of the groups, a comparison of the means of the demographics was undertaken, using $p \leq .05$ to determine significant differences.

Table 6.4: Frequency of survey respondents' Age grouped by Role

	≤49	≥50	Total	Mean	Std.Deviation	Std. Error Mean
Applicant	78%(71)	22%(20)	100%(91)	2.23	.424	.044
Regulator	76%(44)	24%(14)	100%(58)	2.24	.432	.057

The majority of both groups were 49 years of age of under, with less than a quarter over 50 years of age. No significance was determined in the difference of ages between the groups. (Table 6.4)

Table 6.5: Frequency of survey respondents' Education grouped by Role

	Post grad	Under grad	Non Tertiary	Total	Mean	Std.Deviation	Std. Error Mean
Applicant	32%(29)	60%(55)	8%(7)	100%(91)	2.24	.584	.061
Regulator	33%(19)	55%(32)	12%(7)	100%(58)	2.21	.642	.084

The level of education was grouped into three categories: post graduate, under graduate and non-tertiary. Both groups were similarly distributed, with over half being undergraduates and a third post-graduate. No significance was identified for differences between the groups. (Table 6.5)

Table 6.6: Frequency of survey respondents' Gender grouped by Role

	Male	Female	Total	Mean	Std.Deviation	Std. Error Mean
Applicant	32%(29)	68%(62)	100% (91)	1.68	.469	.049
Regulator	14% (8)	86% (50)	100% (58)	1.86	.348	.046

The majority of total respondents were female (Table 6.6). There was a higher proportion of females in the Regulator group (86%) than the Applicants (68%), and a lower level of males in the regulator group (14%) compared with the Applicants (32%). This distribution was found to be significant with $p \leq .001$. The slightly higher mean and lower deviation reflected the high numbers of females in the Regulator group.

Table 6.7: Frequency of survey respondents' Level grouped by Role

	Management	Non-management	Total	Mean	Std.Deviation	Std. Error Mean
Applicant	36%(33)	64%(58)	100%(91)	1.36	.483	.051
Regulator	36%(21)	64%(37)	100%(58)	1.36	.485	.064

The respondent's level was designated into management and non-management. Distribution between the two populations was similar, but there was no significance in this finding. (Table 6.7)

Table 6.8: Frequency of survey respondents' Years grouped by Role

	≤ 5	≥ 6	Total	Mean	Std.Deviation	Std. Error Mean
Applicant	47%(43)	53%(48)	100%(91)	1.53	.502	.053
Regulator	38%(22)	62%(36)	100%(58)	1.62	.489	.064

The majority of Regulators (62%) had been in their roles for over six years compared with 53% of Applicants. This was a significant finding of p=.034. (Table 6.8)

Of the five demographics compared for Applicants and Regulators respondents, significant differences were indicated for gender and years, suggesting a potential for selection bias. More females identified as Regulators who were also more likely to have more years of experience. Surveys of workforce composition find that women make up 78.3% of healthcare personnel and men 21.7% (Australian Government, 2016) suggesting that more female would be expected in responses from the health sector. Findings from a previous study of ethics administrators suggested that administrators were typically in their fourth or fifth decades, female and with more than 6 years of experience in that role (Dunscombe, 2008). On this basis, the groups were considered equivalent.

6.3 Frequency distribution of survey responses

The survey collected data on the adoption and operation of research governance reform in keeping with pressures from the NMA. There were four constructs: the importance of research in public hospitals, the NMA as a coercive force; the NMA as a mimetic force and the NMA as a normative force. Data were collected through respondents ranking a series of items for each construct. The items ranged from broad expectation to the specific experience of the topic. Responses are presented on the basis of the respondent's role: Applicant or Regulator.

6.3.1 Scoring

Demographic data was considered nominal, or discrete classifications of data, in which data are neither measured nor ordered.

Table 6.9: Scoring of respondents' demographics

Variable	Score		
	1	2	3
Age	≤ 49	≥ 50	
Education	Post graduate	Under-Graduate	Non Tertiary
Gender	Male	Female	
Role	Applicant	Regulator	
Level	Management	Non-management	
Years	≤ 5	≥ 6	

The remaining data were considered ordinal and collected through Likert scales. Ordinal data is a categorical, statistical data type where the variables have natural, ordered categories and the distances between the categories is not known. The scales ranged from 1 to 3. The scale for the first question of the set of items was scored as Important (1), Neither important nor unimportant (2) and Unimportant (3). The scale for the remainder of the items was Agree (1), Neither agree nor disagree (2) and Disagree (3). Lower scores indicated support and higher scores indicated rejection of the item. Missing values were replaced with the mean, which did not change the correlation matrix but ensured that missing values were not penalised.

6.3.2 The importance of research in public hospitals

There were five items in this section. Survey respondents were asked to rank their perceptions of the importance healthcare agencies placed on research. There was a similar distribution of responses from both groups. Nearly all respondents indicated strong agreement that research should be regarded as important. (Table 6.10)

Table 6.10: Distribution and frequency of the expectation of research as core business

		Important	Neither Important nor Unimportant	Unimportant	Total	Mean	Std. Deviation	Std. Error Mean
	Role	%(Freq)	%(Freq)	%(Freq)	%(Freq)			
Q1. How important is it that hospitals should regard research as a core activity	*Applicant*	99%(90)	1%(1))	0%(0)	100%(91)	1.11	.348	.036
	Regulator	98%(57)	2%(1)	0%(0)	100%(58)	1.14	.395	.052

Respondents were then asked to order how strongly they agreed to a series of statements about research infrastructure before indicating whether agencies do regard research as a core activity in reality (Appendix E). All respondents indicated substantial support for the need for written site policies and procedures. Both groups also agreed that research performance measures and significant issues (such as ethical breaches) should be reporting to the Board. However, support was stronger in the Regulator group. The highest level of uncertainty and disagreement was recorded for whether research is regarded as a core activity in real life. Of the total number of responses, 84% (125) did not agree that research is regarded as a core hospital activity in real life. Disagreement was stronger in the Applicant group, 72% but Regulators showed greater uncertainty, 16%. (Table 6.11)

Table 6.11: Distribution and frequency of research as core business

		Agree	Neither agree nor disagree	Disagree	Total	Mean	Std. Deviation	Std. Error Mean
	Role	%(Freq)	%(Freq)	%(Freq)	%(Freq)			
Q2 All hospitals undertaking research must have written site policies and procedures	*Applicant*	100%(91)	0%(0)	0%(0)	100%(91)	1.10	.300	.031
	Regulator	98%(57)	2%(1)	0%(0)	100%(58)	1.14	.395	.052
Q3 Research performance measures should be reported to the Board/senior management	*Applicant*	76%(69)	22%(20)	2%(2)	100%(91)	1.79	.863	.090
	Regulator	90%(52)	10%(6)	0%(0)	100%(58)	1.50	.682	.090
Q4 Significant research issues (e.g. ethical breaches) should be reported to the Board/senior management	*Applicant*	79%(72)	18%(16)	3%(3)	100%(91)	1.69	.915	.096
	Regulator	90%(52)	10%(6)	0%(0)	100%(58)	1.45	.680	.089
Q5 In general, hospitals do regard research as a core hospital activity	*Applicant*	14%(13)	13%(12)	72%(66)	100%(91)	4.01	1.137	.120
	Regulator	19%(11)	16%(10)	64%(37)	100%(58)	3.67	1.170	.155

6.3.3 The NMA as a Coercive influence

Data was collected on how the NMA impacted as a coercive influence through seven items. The majority of respondents from both groups supported the importance of the

NMA to hospital research regulation, but Regulator responses were slightly less supportive than Applicants.

Table 6.12: Distribution and frequency of the expectation of the NMA as a coercive influence

		Important	Neither Important nor ... Unimportant	Total	Mean	Std. Deviation	Std. Error Mean
	Role	%(Freq)	%(Freq)	%(Freq)			
Q6. How important should the National Mutual Acceptance (NMA) be to the way hospitals regulate their research?	*Applicant*	90%(82)	8%(8) 1%(1)	100%(91)	1.58	.687	.072
	Regulator	84%(49)	12%(7) 3%(2)	100%(58)	1.58	.823	.109

There was strong support for the first three supporting items of the set: fast authorisation, advice consistency and research governance compliance with the NMA. In all of these items support from both groups was over ninety percent, uncertainty under ten percent and disagreement under three percent. Regulators were slightly less supportive than applicants. (Table 6.12)

Table 6.13: Distribution and frequency of the NMA as a coercive influence

	Role	Agree	Neither agree nor disagree	Disagree	Total	Mean	Std. Deviation	Std. Error Mean
		%(Freq)	%(Freq)	%(Freq)	%(Freq)			
Q7.Research authorisation should be as fast as possible	*Applicant*	97%(88)	3%(3)	0%(0)	100%(91)	1.22	.490	.051
	Regulator	93%(54)	5%(3)	2%(1)	100%(58)	1.67	.659	.087
Q8.Hospital advice on how to apply for multi-site research review should be consistent with NMA advice	*Applicant*	96%(87)	4%(4)	0%(0)	100%(91)	1.36	.568	.060
	Regulator	91%(53)	5%(3)	2%(1)	100%(58)	1.40	.678	.090
Q9.Research governance managers should be encouraged to comply with NMA operating procedures	*Applicant*	93%(85)	7%(6)	0%(0)	100%(91)	1.49	.621	.065
	Regulator	91%(53)	9%(5)	0%(0)	100%(58)	1.48	.655	.086
Q10.It should be the responsibility of senior hospital management to ensure that research complies with NMA targets	*Applicant*	76%(69)	18%(16)	5%(5)	100%(91)	1.82	.955	.101
	Regulator	74%(43)	19%(11)	7%(4)	100%(58)	1.84	1.073	.141
Q11.All research reviews should be undertaken with the same forms and processes	*Applicant*	69%(63)	26%(24)	4%(4)	100%(91)	1.85	.999	.105
	Regulator	57%(33)	34%(20)	9%(5)	100%(58)	2.12	1.141	.150
Q12.In general, the NMA is a powerful influence on hospital research governance	*Applicant*	41%(37)	52%(47)	8%(7)	100%(91)	2.59	.906	.095
	Regulator	50%(29)	36%(21)	14%(8)	100%(58)	2.53	.922	.121

In the last three questions, support across both groups diminished while uncertainty and disagreement increased. The lowest level of support was recorded for the final item of the set where respondents were asked to rank their experiences of the impact of the NMA. Half of Regulators indicated support that the NMA did influence governance practices but 62% (47) of Applicants indicated uncertainty and 8% (7) indicated disagreement. (Table 6.13)

6.3.4 The NMA as a Mimetic influence

The mimetic items explored respondents' perceptions of the NMA influencing exploring and adopting practices of their peers. There were six items, ranging from a general expectation to respondents' experiences of the NMA setting standards.

Similar to the responses for Coercive impact, greatest support was provided for the more generic questions (Q 13). All respondents indicated support for the NMA setting a target approval time, but support was stronger in the Applicant group, 98%, compared to 88% for Regulators. Regulators also showed slightly more uncertainty, 9%, and disagreement 3%. Regulator responses also showed a high standard deviation, signifying that the data points were spread out over a wider range of values than the Applicant group. (Table 6.14) This finding suggests less unity in the Regulator group and will be discussed further in Chapter Eight.

Table 6.14: Distribution and frequency of the expectation of the NMA as a mimetic influence

		Important	Neither Important nor Unimportant	Unimportant	Total	Mean	Std. Deviation	Std. Error Mean
	Role	%(Freq)	%(Freq)	%(Freq)	%(Freq)			
Q13. How important is it for the NMA to set a standard time by which projects should be approved?	*Applicant*	98%(89)	2%(2)	0%(0)	100%(91)	1.31	.510	.053
	Regulator	88%(51)	9%(5)	3%(2)	100%(58)	1.59	.795	.104

Regulators consistently indicated more support than Applicants in the remaining items of this section while the Applicants indicated greater uncertainty and disagreement. (Table 6.15). Greatest support was shown by the Regulators towards research personnel networking and benchmarking performance as well as the opportunity to consult with peers in times of change. Slightly less Regulator support was indicated for research governance managers looking to the practices of others and that the NMA does set a standard approval time.

These results indicate that the Applicants' perspectives is dominated by the outcome of the research review process but the Regulators are more concerned with the practices of research governance.

Table 6.15: Distribution and frequency of the NMA as a mimetic influence

	Role	Agree	Neither agree nor disagree	Disagree	Total	Mean	Std. Deviation	Std. Error Mean
		%(Freq)	%(Freq)	%(Freq)	%(Freq)			
Q14: Research governance managers should have regular opportunity to network	*Applicant*	77%(70)	22%(20)	1%(1)	100%(91)	1.90	.817	.086
	Regulator	98%(57)	2%(1)	0%(0)	100%(58)	1.38	.524	.069
Q15: To improve research authorisation times, research governance managers should first look to practices of other research offices	*Applicant*	70%(64)	28%(25)	2%(2)	100%(91)	2.02	.856	.090
	Regulator	74%(43)	19%(11)	7%(4)	100%(58)	1.97	1.025	.135
Q16: When hospitals benchmark their research performance, they should compare to other like organisations	*Applicant*	82%(75)	16%(15)	1%(1)	100%(91)	1.75	.811	.085
	Regulator	93%(54)	7%(4)	0%(0)	100%(58)	1.48	.628	.082
Q17: The ability to consult with other research governance managers is more important in times of change	*Applicant*	68%(62)	31%(27)	1%(2)	100%(91)	2.00	.861	.091
	Regulator	91%(53)	9%(5)	0%(0)	100%(58)	1.55	.654	.086
Q18. The NMA does set a standard approval time	*Applicant*	65%(58)	31%(30)	3%(3)	100%(91)	2.00	.910	.097
	Regulator	72%(42)	21%(12)	7%(4)	100%(58)	1.96	.972	.130

6.3.5 The NMA as a Normative influence

Normative influence involves inter-agency phenomenon, exerted through rules and requirements that organisations must abide by to obtain the expected support and legitimacy from the environment in which they operate. For example, normative influence relates to those factors that serve to encourage inter-organisational standardisation, such as professional education, training and standards. In this section of

the survey, respondents were asked to evaluate the impact of professional standards in research governance. There were five items included in the normative construct of the survey items. Respondents were asked to rank their expectation of the need for professional standards in research governance; then to order how strongly they agreed with a series of supporting questions before indicating the degree to which they agree that research offices currently have professional standards.

Table 6.16: Distribution and frequency of the expectation of the NMA as a normative influence

	Role	Important	Neither Important nor ... Unimportant	Total	Mean	Std. Deviation	Std. Error Mean
		%(Freq)	%(Freq)	%(Freq)			
Q19. How important is it that there are professional standards in research governance?	*Applicant*	91%(83)	8%(8)	0%(0)	100% (91)	1.61	.631	.066
	Regulator	100%(58)	0%(0)	0%(0)	100% (58)	1.19	.395	.052

While both groups responded positively to this item, all Respondents indicated agreement, whereas there was 8% of uncertainty indicated by the Applicant group.

Respondents were then asked to rank the degree to which they supported a series of items that related to how the NMA should influence governance practice with healthcare agencies. Regulators consistently indicated greater support than Applicants, but there was a persistent level of uncertainty in responses to all items. .

In relation to common position descriptions and similar responsibilities for research governance staff, 84% of Regulators indicated agreement but 14% indicated uncertainty and 2% indicated disagreement. Of the Applicant responses 69% indicated agreement but a third indicated uncertainty. Similarly, more Regulators, 88%, agreed to a career path within research governance teams but 12% indicated uncertainty. Of the Applicants, 42% indicated uncertainty and 1% disagreement. (Table 6.17)

Table 6.17: Distribution and frequency of the NMA as a Normative influence.

	Role	Agree %(Freq)	Neither agree nor disagree %(Freq)	Disagree %(Freq)	Total %(Freq)	Mean	Std. Deviation	Std. Error Mean
Q20. Research governance staff should have common position descriptions and similar responsibilities	*Applicant*	69%(63)	31%(28)	0%(0)	100%(91)	2.04	.759	.080
	Regulator	84%(49)	14%(8)	2%(1)	100%(58)	1.62	.791	.104
Q21. There should be a career path within research governance teams	*Applicant*	57%(52)	42%(38)	1%(1)	100%(91)	2.27	.790	.083
	Regulator	88%(51)	12%(7)	0%(0)	100%(58)	1.43	.704	.092
Q22. Research governance staff should have agreed professional standards	*Applicant*	74%(67)	26%(24)	0%(0)	100%(91)	1.90	.790	.083
	Regulator	91%(53)	9%(5)	0%(0)	100%(58)	1.34	.637	.084
Q23. Research governance units do have professional standards	*Applicant*	23%(21)	67%(61)	10%(9)	100%(91)	2.86	.739	.077
	Regulator	43%(25)	34%(20)	23%(13)	100%(58)	2.60	1.042	.137

More Regulators, 91%, supported the need for professional standards than Applicants, 74%. More Applicants, 26%, indicated uncertainty than Regulators, 9%. The final item of this set, where respondents were asked to rank whether research governance units do have professional standards in reality (Q23), showed the lowest levels of agreement. Of the Applicants, 67% indicated uncertainty and 10% disagreed. Of the Regulators, 34% indicated uncertainty and 23% disagreed. Previous findings for coercive and mimetic influences indicated that the Applicants' perspectives is dominated by the outcome of the research review process and the Regulators are more concerned with the practices of research governance. The findings in this section suggest a lack of standardisation across the research governance sector.

6.3.6 Independent Samples Test

Independent Samples t-Test (or Student t-test) was used to compare the means of the Applicant and Regulator groups to determine any statistical evidence of significant differences in the associated population means. Levene's Test of Equality of Variances was applied using an Alpha of 0.05 as the cut-off for significance.

The null hypothesis states that there no difference between the means of both groups. Findings where the p-value or probability value is greater than .05 supports the null hypothesis and those results were discounted. Findings where $p \leq .05$ meant that the variance was not caused by chance and the magnitude of the effect and the direction became of interest. Of the 22 survey items analysed for significance of their distribution around the role of the respondent, six showed some significance.

Table 6.18: Independent samples test of survey responses

		Levene's Test for Equality of Variances		t-test for Equality of Means	
		F	Sig.	t	df
Q7	Equal variances assumed	12.284	.001	-4.796	147
	Equal variances not assumed			-4.497	96.608
Q13	Equal variances assumed	16.779	.000	-2.607	147
	Equal variances not assumed			-2.374	86.966
Q14	Equal variances assumed	4.558	.034	4.326	147
	Equal variances not assumed			4.748	146.988
Q19	Equal variances assumed	37.320	.000	4.544	146
	Equal variances not assumed			4.997	145.920
Q22	Equal variances assumed	4.184	.043	4.510	147
	Equal variances not assumed			4.729	138.959
Q23	Equal variances assumed	21.047	.000	1.737	147
	Equal variances not assumed			1.614	93.329

The importance of research in public hospitals

No significance was indicated for any differences between the Applicant and Regulator groups.

Coercive influence

In regard to the NMA impacting as a coercive influence, significance was found for responses to Q7, that research authorisation should be as fast as possible ($p = .001$). Regulators were slightly less supportive than Applicants and had a higher standard deviation, signifying that the data points were spread out over a wider range of values than the Applicant group.

Mimetic influence

In relation to Q13, where respondents ranked the importance of the NMA setting standard time by which projects should be approved, Applicants showed greater support than Regulators. Regulators also showed at higher standard deviation, indicating a greater breadth of response. ($p \leq .001$). In contrast, Regulators were more supportive of Q14, that research governance managers should have regular opportunity to network. While 98% of Respondents indicated support, only 77% of Applicants indicated support and 22% indicated uncertainty ($p = .034$).

Normative influence

There were three items considered significant in the section exploring the NMA as a normative influence. In relation to the importance of professional standards in research governance (Q19), there was greater support from the Regulator group (100%) than the Applicant group which indicated 8% of uncertainty. There was a higher mean and standard deviation for the Applicant group. ($p \leq .001$) In relation to Q 22, Regulators, 91%, were also more supportive of professional standards for research governance staff than Applicants, 74%. A greater number of Applicant respondents, 26%, indicated uncertainty than the Regulators 9%. The Applicant mean and standard deviation were higher than the Regulator ($p = .043$).

Over half of both groups did not support the existence of professional research governance standards. Regulators indicated 34% of uncertainty and 23% disagreement. The uncertainty in Applicant responses was almost double, at 67%, but they indicated a lower disagreement at 10% ($p \leq .001$).

Together, findings from these six items suggest that Applicants are more likely to be supportive of the outcome of the research review whereas Regulators are concerned with how research governance is structured. These findings also suggest that the respondent's role is not the only influence on how they view the impact of a national system on hospital practices.

6.3.7 Uncertainty

There were four sections of the survey in which scales were used to collect data. The items respondents were asked to rank ranged from generic to specific. The first item asked respondents to rank their expectation of the section topic and then the last item asked them to rank their experiences of the topic. Uncertainty, where the respondent was neither supportive nor unsupportive of the item, was present in all sections. Figures 6.1 and 6.2 present the uncertainty response to each question in order of the questions asked.

In respect to the importance of research in public hospitals, uncertainty increased in response to whether research performance or adverse issues should be reported to the Board and remained at over twenty percent for respondent experience.

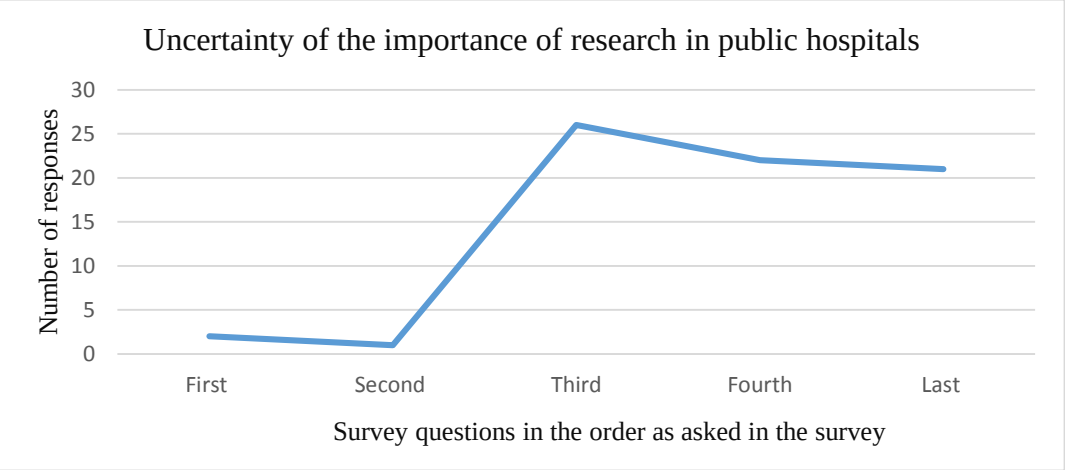

Figure 6.1: Measures of uncertainty in the importance of research in public hospitals

Increasing uncertainty was also shown in the sections exploring how the isomorphic impact of the NMA was perceived. Uncertain responses to the coercive impact of the NMA increased on the fifth item, where respondents were asked to rank whether responsibility for compliance with the NMA rested with senior managers. The highest level of uncertainty was recorded in response to respondents' experiences of the influence of the NMA.

Uncertainty responses to the impact of the NMA as a mimetic influence peaked twice. It first increased on the third item which stated that to improve performance, research

governance managers should look to their peers and then again on experience. The highest level of uncertainty was recorded in relation to the NMA acting as a normative influence. Similar to the section on mimetic influence, there are two peaks in normative uncertainties. The first peak is at the fourth question, whether research governance staff should have professional standards and the second reflects respondents' experiences of standards in governance units.

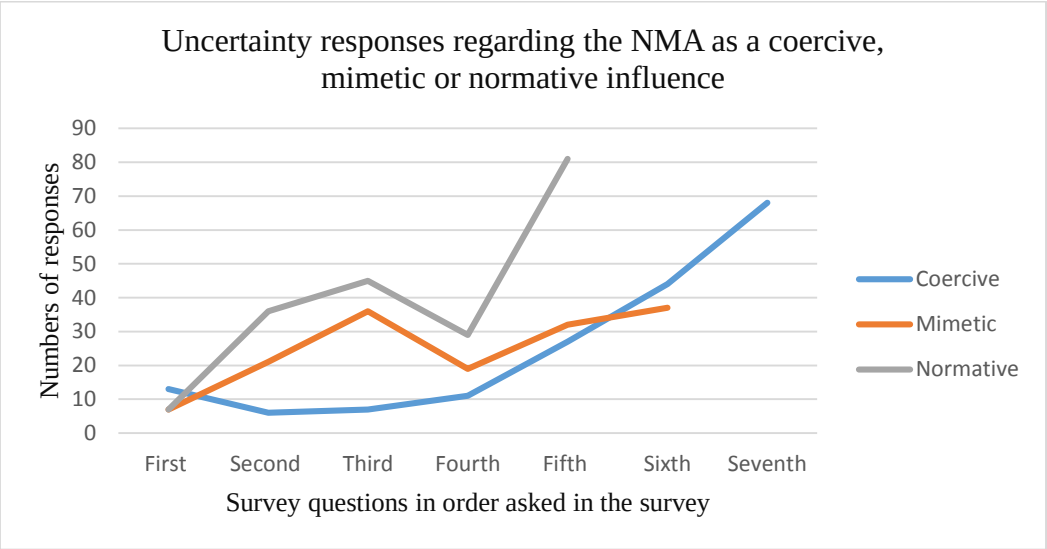

Figure 6.2: Measures of uncertainty of the NMA isomorphic influence

The frequency and distribution of responses demonstrate differences between expectation and experiences of reality in all sections of the survey (adoption of the NMA) and that respondents were more uncertain or less in agreement on how the NMA functioned within organisations (operations of the NMA).

6.4 Statistical analysis

The numbers of uncertain responses in all sections of the survey responses suggested that there were other factors that influenced respondent perspectives. Statistical analysis was undertaken to determine any latent or unseen variables and to explore relationships between the variables in preparation to test the hypothesis. The results of the survey items were assigned numerical scores.

6.4.1 Scoring of demographics

Table 6.19 presents the values associated with respondent demographics. Because of the limitation of the sample size, data was regrouped into two categories for each variable.

Table 6.19: Scoring of the respondent demographics

	1	**2**	**3**
Age	≤ 49	≥ 50	
Education	Post Grad	Under-grad	Non-Tertiary
Gender	Male	Female	
Role	Applicant	Regulator	
Level	Management	Non-management	
Years	≤ 5,	≥ 6	

6.4.2 Scoring of Likert scales

The Likert scales used in the survey ranged from one to three, with one indicating the strongest agreement to the item and three indicating the strongest disagreement. The values used for ranking the expectation of an items importance were as follows:
1: Important, 2: Neither important nor unimportant and 3: Unimportant. The values used for ranking the remaining statements were 1: Agree, 2: Neither agree nor disagree and 3: Disagree. Consequently higher scores on an item indicted greater disagreement and lower scores indicated agreement.

6.5 Factor analysis

Factor analysis was used as an exploratory measure of the robustness of the survey, the reliability of the constructs and the validity of the variables in each construct. All Likert-scaled variables were subjected to factor analysis. The principal component method was used to extract the factors. This method is the most frequently used approach and transforms correlated variables into a new set of principal components not correlated to each other. The linear combination of these components, called factors, then account for the variance in the data.

The key concept of factor analysis is that multiple observed variables have similar patterns of responses due to their association with a latent (i.e. not directly measured) factor. Thus researchers are able to explore concepts that are not easily measured directly by collapsing a large number of variables into a few interpretable underlying factors.

Factor loading represents the correlation between the original variable and its factors, and correlation coefficients were used for determining the significance level for the interpretation. Loading exceeding 0.70 is considered indicative of a well define structure, and for the purpose of factor loading this measure was used to determine variables and factor loadings for each construct in this study. The eigenvalue was calculated for each factor extracted and was used to determine the number of factors to extract. The eigenvalue for a given factor measures the variance in all the variables which is accounted for by that factor. A cut-off value of 1 is generally used to determine factors based on eigenvalues. In order to produce meaningful data, items from the survey that fell below the cut-off value were removed from the analysis until a loading of 72% was reached. This resulted in six factors, shown in Table 6.20. The Scree test, which displays the eigenvalues for each factor, was used as part of the decision criteria for retaining factors (Figure 6.3).

After extracting the factors, the factors were rotated to better fit the data. The Varimax rotation method, an orthogonal rotation method, was used.

Table 6.20: Total Variance Explained of NMA impact

	Initial Eigenvalues			Rotation Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.343	21.717	21.717	2.959	16.794	16.794
2	2.538	12.689	34.406	2.493	14.467	31.261
3	2.019	10.096	44.502	2.445	13.227	44.488
4	1.482	7.408	51.910	1.994	11.968	56.456
5	1.232	6.160	58.070	1.532	8.661	65.117
6	1.086	5.428	63.498	1.276	7.381	72.498
7	.889	4.447	67.945			
8	.864	4.319	72.264			
9	.823	4.116	76.380			
10	.729	3.643	80.022			
11	.656	3.282	83.304			
12	.598	2.989	86.293			
13	.503	2.513	88.807			
14	.472	2.360	91.166			
15	.427	2.135	93.301			
16	.394	1.969	95.270			
17	.274	1.368	96.639			
18	.266	1.332	97.971			
19	.238	1.190	99.160			
20	.168	.840	100.000			

Extraction Method: Principal Component Analysis.

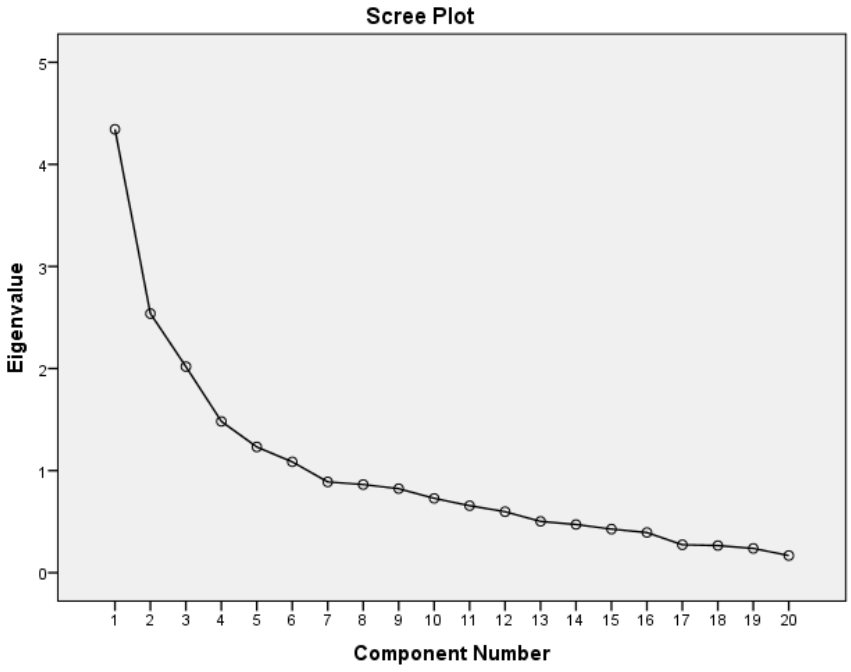

Figure 6.3: Scree plot of Principal Component Analysis identifying six factors

The six factors, together with the contributing survey items, are presented in the following, Table 6.21.

Table 6.21: Six factors of NMA influence and contributing variables

Factor		Explanation	Item no.	Survey Item
1	**Comparison**	*Comparison with peers*	14	Research governance managers should have regular opportunity to network
			15	To improve research authorisation times, research governance managers should first look to practices of other research offices
			16	When hospitals benchmark their research performance, they should compare to other like organisations
2	**Authority**	*Authority of the NMA*	1	How important is it that hospitals should regard research as a core activity?
			9	Research governance managers should be encouraged to comply with NMA operating procedures
			13	How important is it for the NMA to set a standard time by which projects should be approved?
3	**Standards**	*Endorsement of professional research governance standards*	20	Research governance staff should have common position descriptions and similar responsibilities
			21	There should be a career path within research governance teams
			22	Research governance staff should have agreed professional standards
4	**Reporting**	*Reporting to the Board*	3	Research performance measures should be reported to the Board/senior management
			4	Significant research issues (e.g. ethical breaches) should be reported to the Board/senior management
5	**Standard Importance (Stan. Import)**	*Importance of the adoption of professional standards in research governance*	19	How important is it that there are professional standards in research governance?
6	**NMA Importance (NMA Import)**	*Importance of NMA to hospital research regulation*	6	How important should the National Mutual Acceptance (NMA) be to the way hospitals regulate their research?

While the factors appear to have some crossover with the constructs of Institutional Isomorphism on which the survey was based, they represent underlying beliefs or perspectives. The factors were understood as the following:

Factor one, Comparison, appears to be related to assessment of peers. It includes variables related to opportunity to appraise the activities of others, suggestive of a mimetic influence.

Factor two, Authority, appears to be related to the perceived authority of the NMA. The associated variables reflect research legitimacy and the need for the NMA to establish a target. The expectation of management compliance is also loaded into this factor.

Factor three, Standards, suggests the operation of professional research governance. It includes the expectations of career paths, position descriptions and standards, reflective of a normative influence.

Factor four, Reporting, also suggests operation of research governance through involvement with the board. The associate variables involve reporting research performance and adverse events to the board.

Factor five, Standard Importance (Stan. Import), was comprised of one variable evaluating the need for professional standards in research governance.

Factor six, NMA Importance (NMA Import), was also comprised of a single variable evaluating the importance of the NMA to hospital regulations.

The crossover between the factors indicates the difficulties of discerning the differences between isomorphic influences. Regression analysis was then applied to these factors and the participant demographics. .

6.6 Regression analysis

Regression analysis was used for estimating the relationships among variables. This statistical modelling focused on the relationship between a dependent variable and one or more independent variables (or 'predictors'). In this study, regression analysis provided a tool to understand how the typical value of the dependent variable (or 'criterion variable') changes when any one of the independent variables is varied, while the other independent variables are held fixed.

Standardised coefficients or beta coefficients are the estimates resulting from a regression analysis. They are standardised so that the variances of dependent and independent variables are 1. Therefore, standardised coefficients refer to how many standard deviations a dependent variable will change, per standard deviation increase in the predictor variable. Standardisation addresses the question of which of the independent variables have a greater effect on the dependent variable in a multiple regression analysis, when the variables are measured in different units of measurement.

In this analysis, the relationships between the themes were explored to determine which, if any, impacted on the others and whether this led to prediction. Results were reported using beta (B), which represents the slope of the line between the predictor variable and the dependent variable.

6.6.1 Comparison

The factor Comparison referred to comparison between peers. This is a central concept of mimetic isomorphism, related to organisations observing and copying a more successful peer. Using Comparison as the dependant variable and the remaining factors as independent variables, 35.5% of the variance was explained by regression analysis Table 6.22). The highest scores were from Standards, Reporting and Years.

Table 6.22: Coefficient values when Comparison is the dependent variable

Variable	Beta (B).
Standards	.383
Reporting	.411
Years	-.848

There is a positive relationship between Comparison and Standards and Reporting but a negative relationship with Years. Thus for every one unit increase of the variable Standards, the dependent variable, Comparison, increases by .383 units, and for every one unit increase of the variable Reporting the dependent variable, Comparison, increases by .411 units. However, for every one unit increase of the variable Years, the dependent variable, Comparison, decreases by .848. This infers that less experienced personnel were more likely to support comparison and reporting of research governance practices than more experienced.

6.6.2 Authority

The factor Authority denoted the authority of the NMA, which is a tenet of the NMA acting as a coercive pressure on organisational behaviour. Of the variables contributing to this factor, NMA Import showed the highest *B* value of .87, suggesting that perception of the authority of the NMA was associated with an expectation of a link between the NMA and research governance. Using Authority as the dependant variable and the remaining factors as independent variables, 38.6% of the variance was explained by regression analysis. (Table 6.23)

Table 6.23: Coefficient values when Authority is the dependent variable

Variable	Beta (B).
NMA import	.87
Years	-.58
Role	.417
Comparison	.088
Age	.413

A positive relationship was found between Authority and NMA Import, Role, Comparison and Age, but, like the factor Comparison, a negative relationship with Years. Thus, a higher scoring for NMA Import, Role, Comparison and Age was associated with higher scoring for Authority but a lower scoring for Years is associated with a higher scoring for Authority. Older, more experienced Regulators were less likely to recognise the authority of the NMA.

6.6.3 Standards

The factor Standards indicated the degree to which respondents endorsed criteria for professionalisation of research governance personnel, such as common position descriptions and career paths. Pressures from professional standards, which are inter-organisational, provide a normative influence that encourages similar behaviours across different organisations. Using Standards as the dependant variable and the remaining factors as independent variables, 46.9% of the variance was explained by regression analysis (Table 6.24). The highest scores were from Stand. Import, Comparison and Years but a negative relationship was found with Role and Gender.

Table 6.24: Coefficient values when Standards is the dependent variable

Variable	Beta (B).
Stand. Import	1.104
Comparison	.326
Role	-1.104
Years	.685
Gender	-.606

A positive relationship was found between Standards and Stan.Import, Comparison and Years. Stan Import. The highest score was for Stan.Import, which ranked expectation of professional standards in research governance, so that for every unit increase of Stan.Import, Standards increased by 1.104.

A negative relationship was found between Standards and Role and Gender. Thus for every one unit increase of the variable Role, the dependent variable, Standards, decreased by 1.104. Respondents who indicated their role as Regulator (scored as 2) were more likely than Applicants (scored as 1) to indicate support for professional research governance standards. For every one unit increase of the variable Gender, the dependent variable, Standards, decreased by .606. Females (scored as 2) were more likely than males (scored as 1) to indicate support for professional research governance standards.

The inference is that female Applicants, who had a low expectation of professional standards in research governance, were less likely to endorse professional criteria for research governance, such as common position descriptions and career paths.

6.6.4 Reporting

The factor Reporting referred to reporting of research performance and adverse events to the Board of Directors as part of the organisational governance structure. If research is a core activity, then there would need to be an organisational pathway to account for research performance. This would also denote the perceived legitimacy of research within the organisations. Using Reporting as the dependant variable and the remaining factors as independent variables, 26.7% of the variance was explained by regression analysis. (Table 6.25)

Table 6.25: Coefficient values when Reporting is the dependent variable

Variable	Beta (B).
Comparison	.236
Stan. Import	.772
Level	-.485

A positive relationship was found between Reporting and Comparison and Stand. Import. The highest score was indicated for Stan.Import, which ranked expectation of professional standards in research governance. Thus every one unit increase of the variable Stan.Import, the dependent variable, Reporting, increases by b=.772 units. For every one unit increase of the variable Comparison, the dependent variable, Reporting, increases by .236 units. A negative relationship was found between Reporting and Level. For every one unit increase of the variable Level, the dependent variable, Reporting, decreases by b= .485.

The inference from this findings is that managerial respondents (scored at 1) were more likely to support reporting to the Board than non-managerial (scored at 2).

6.6.5 Importance of professional standards (Stan import)

Professional standards are a basis to normative pressures. Stan.import related only to the expectation of professional standards in research governance. Using Stan.Import as the dependant variable and the remaining factors as independent variables, 33.2% of the variance was explained by regression analysis (Table 6.26). There was a positive relationship between Stan. Import and the variables Standards and Reporting.

For every one unit increase of the variable Standards, led to an increase in Stan Import of b=.13 and every one unit increase of the variable Reporting led to an increase in Stan Import of b=.096.

Table 6.26: Coefficient values when Stan Import is the dependent variable

Variable	Beta (B).
Standards	.13
Reporting	.096

The inference is that respondents who endorsed professional criteria for research governance personnel and reporting to the Board, were more likely to rate expectation of professional standards in research governance more highly.

6.6.6 NMA Import

NMA Import related to expectation of the influence of the NMA on the way hospitals regulate their research. Using NMA Import as the dependant variable and the remaining factors as independent variables, 29.4% of the variance was explained by regression analysis. (Table 6.27)

Table 6.27: Coefficient values when NMA Import is the dependent variable

Variable	Beta (B).
Authority	.317

Analysis found a positive relationship between NMA Import and Authority. Thus for every one unit increase of the variable Authority, the dependent variable, NMA Import, increased by b=.317 units. Findings on the factor Authority found that respondents of the 50 and over age group were less likely to perceive the authority of the NMA. The inference is that personnel from the older age bracket were less likely to expect the NMA to impact hospital research governance practices.

Figure 6.4 provides a summary of relationships between dependant and independent variables and the relevant demographics.

	Independent variables											
Dependant variable	Comparison	Authority	Standards	Reporting	Stan. import	NMA Import	Age	Education	Gender	Role	Level	Years
Comparison			+	+								-
Authority	+					+	+			+		-
Standards	+				+				-	-		+
Reporting	+				+						-	
Stan. import			+	+								
Import NMA		+										

Positive relationship between the dependant and independent variable

Negative relationship between the dependant and independent variable

Figure 6.4: Summary of relationships between the factors identified through factor analysis and respondent demographics

6.7 Tests of hypotheses

6.7.1 Influences on the adoption of the NMA

The majority of reform in the public sector is initiated through government policy (Victorian State Government, 2016a, 2016b), inferring that adoption involves the organisation recognising the need to appear to be acting in compliance to government objectives. In relation to the concept of NMA legitimacy, the analysis identified two factors, Authority and Reporting.

The factor Authority of the NMA, "Authority", was comprised of three items where respondents ranked the importance of research in hospitals and compliance to the NMA. As expected, Authority showed a positive relationship with perceived importance of the NMA, "NMA import", which suggests that adoption of the NMA was positively related to organisational recognition of research activity (legitimacy).

The factor "Reporting" referred to use of an organisational pathway to account for research performance to denote the perceived legitimacy of research within the organisations. Reporting showed a positive relationship with the factors Comparison and to the importance of professional standards (Stan Import). There was a negative relationship with respondent level, indicating that higher organisational levels were more supportive of reporting to the Board.

H1 stated that, in relation to research governance reform, adoption of the NMA was positively related to organisational recognition of research activity (legitimacy). These findings suggest support for H1, and that adoption of the NMA was positively related to organisational recognition of research activity (legitimacy).

6.7.2 Influences the operation of research governance reform

The operation of research governance reform reflects the capacity of an organisation to act upon pressures that influence its direction. The constructs from the conceptual model suggested that the NMA would influence reform through coercive, mimetic and normative isomorphic influences. Additionally, it was hypothesised that this association would be moderated by the respondent role, such that it would be more salient to those from the Regulator group.

Coercive isomorphism

Coercive pressures to act is similar ways develop as organisations face similar environmental constraints. Analysis found a positive relationship between the expected importance of NMA to hospital research regulation (NMA Import) and the perceived authority of the NMA (Authority). The factor, "NMA Import", was based on a single survey item where respondents were asked to rank the impact of the NMA on research regulation in hospitals. The factor "Authority" of the NMA was comprised of three items where respondents ranked the importance of research in hospitals and compliance to the NMA. The positive relationship between NMA Import and Authority suggests that coercive impact of the NMA was positively related to the perception of the importance of research and the authority of NMA.

H2a stated that, in relation to research governance reform, the operation of the NMA was positively related to acknowledgment of the authority of NMA (Coercive isomorphism). Findings from the study supports H2a.

Mimetic isomorphism

Analysis found positive relationships between support for comparison of research governance units (Comparison) and endorsement of professional research governance standards (Standards) as well as reporting on research activities to the Board (Reporting). It also found a negative relationship between Comparison and the years that respondents had spent in that role (Years).

Intentional comparison between peers is a basic tenet of mimetic isomorphism. Mimetic isomorphism is when organisations deliberately set out to identify the actions of those more successful in a specific area, with a view to modifying their own practices. These findings suggested that the NMA could only provide a mimetic influence if there was support for governance standards and research being part of the organisational governance framework.

H2b stated that in relation to research governance reform, the operation of the NMA was positively related to perception of the need to compare with peers (Mimetic isomorphism). These findings suggest that the operation of governance reform was positively related to support of comparison with peers (Mimetic isomorphism) and that H2b is supported.

Normative isomorphism

Normative influences are developed from inter-organisational pressures, such as professional standards that encourage similar behaviours across different agencies. In predicting reform was related to endorsement of research governance standards (Normative isomorphism), the relevant factors were the adoption of professional standards in research governance (Stan Import) and the endorsement of professional research governance standards (Standards). Support for professional standards was associated with operational practices such as cross-unit comparisons and internal governance practices.

H2c stated that, in relation to research governance reform, the operation of the NMA was positively related to endorsement of research governance standards (Normative isomorphism). The findings of this study supports H2c.

Impact of respondent role

The third hypothesis predicted that perception of adoption and operation of the NMA was positively related to respondent role, such that the effect will be stronger for Regulators than other demographics. Role was found to have a positive relationship to the perception of the importance of the NMA (coercion), more salient to the Regulator group. However, H3 is only partially supported because age and years were also significant. Age had a positive relationship showing personnel from the older age bracket (50 years and greater) were less likely to expect the NMA to impact hospital research governance practices. More experienced personnel (those who had been in the role 6 or more years) were showed to be more supportive of the authority of the NMA.

In relation to the NMA as a mimetic influence, analysis also found a negative relationship between Comparison and the years that respondents had spent in that role (Years). Respondents with greater experience were more likely to support comparison between research governance units. However, in relation to the NMA as a normative influence, analysis found a positive association with Years, meaning that those with greater experiences in the role were less supportive of governance standards. Males were also less supportive of standards in research governance.

He3 stated that in relation to research governance reform, perception of adoption and operation of the NMA was positively related to respondent role, such that the effect will be stronger for Regulators than other demographics. These results point to only partial support for H3, showing the support of the NMA providing normative pressure was moderated by Role, Years and Gender (more salient to Regulators, less experienced and female personnel).

6.7.3 Summary of the hypotheses

A summary of hypotheses is provided in Table 6.28. In particular, this table shows how demographics moderate the association between the dependant and independent variables and provides an explanation of how this is interpreted.

Table 6.28: Summary of the hypotheses

H	Endorsed	Dependent variable	Independent variables	Variables Moderators	Explanation
H1	Yes	Authority Reporting	NMA import	Role Years, Age Level	Support for research importance is more salient to regulators, younger personnel more experienced and higher levels
H2a	Yes	Importance of the NMA	Authority of the NMA	Role Years Age	Coercive impact of the NMA depends of recognition of authority ;more salient to regulators, younger and more experienced personnel
H2b	Yes	Comparison	Standards Reporting	Years	Mimetic influence supported by those who support standards and internal governance ; more salient
H2c	Yes	Importance of standards	Standards,	-	Normative influence supported by those who support standards
H3	Partially	Operation of the NMA	Role	Role Age Gender Level Years	While role impacts on perceptions of the NMA, it is not the only moderating demographic. Years of experience is also consistently significant.

Based on the research findings from phase one, the hypotheses were confirmed and it can be surmised that the NMA was associated with isomorphic influence and that Regulators were more supportive of research governance operations. However, analysis also showed that individual isomorphic influences were not distinct and that there were several demographics that impacted on perceptions of the NMA.

6.8 Qualitative responses

Respondents were also invited to respond to three questions:

- What systems, processes or initiatives have you encountered (or implemented) that assist research review?
- What major difficulties have you encountered in the research review process? How would you resolve these?
- Would you like to make any other comments?

Of the 149 survey respondents, 94 made one or more comments, from which five themes were developed. Respondents noted that factors within each theme operated as facilitators as well as inhibitors of a streamlined review system. The themes that respondents felt impacted identified from these responses included:

- Leadership
- Standardisation
- Communication

6.8.1 Leadership

National leadership

Several respondents indicated the need for Australia to develop a national system of research review across all jurisdictions. Their comments indicated that leadership was significant at all levels; to formulate and uphold strategic direction as well as motivating employees to relevant goals. National leadership was required to "ensure consistency across research sites" (Survey 43, Applicant)

> Research is vital and for Australia to be able to compete on an international level, clinical research and trials needs to be recognised by the institution as core activity (Survey 4, Regulator).

Respondents observed limitation of inter-jurisdictional directives as a critical issue.

> NHMRC [National Health and Medical Research Council] [and] State governments could assist more by mandating certain practices and arranging mentoring/preceptorship opportunities (Survey 3, Regulator)

> There are many inconsistencies, including jurisdictional differences which add complexity to the review process. A resolution may be to simplify differences in legislation or perhaps, more easily

> jurisdictional requirements relating to research governance which may not be a legislative requirement (Survey 19, Regulator).

State leadership

Responsibly for the NMA for each jurisdiction rested with the relevant states or territories, which have individual legislative and regulatory frameworks.

> When this streamlining started it seemed like there would be one system for all research - now it differs depending who is involved (e.g. public, private, university) or low risk or not or clinical trial or not. Ethics committees make their own rules - different states do it differently (Survey 19, Regulator).

Participating organisations

The operational responsibility for the NMA in Victoria rests with the participating healthcare agencies, seven of which also hold the Victorian HRECs certified to review for the NMA.

> When sites have common processes so the processes are relatively the same in different sites. When the PI or the CPI know their responsibilities e.g. respond to emails [and] requests in a timely manner (Survey 47, Applicant)

However respondents also noted marked differences between different organisational conditions.

> There appears to be a lot of variability in quality between different central HRECS, with apparently little accountability (Survey 28, Applicant)

> Different forms and processes for individual ethics committees who are reviewing/central site. Appalling standards of central reviewing committees. "Rubber stamping" not reviewing of documents by

> central reviewing receiving ethic/governance offices (Survey 45, Applicant)

Respondents expressed concerns that their research sectors, including obligations to the NMA, did not have a more overt presence.

> It makes me really angry that we still have differences between ethics committees, RGOs and general dealings with different hospitals. I think that hospitals need to realise that clinical practice and research are intertwined (Survey 81, Applicant)

Several respondents highlighted the limited knowledge and commitment from their senior management.

> Nor am I sure that our CEO really knows about us, except as a photo opportunity in research week (Survey 107, Regulator).

> I don't believe that we are anything but a curiosity to most of the executive … We have research week , that the CEO attends, but even still I don't think that he sees researchers. I think he sees it as a university thing (Survey 100, Applicant).

Thus, respondents felt that the roles of the board and senior management were also restricted.

> At this stage, I don't think it's a good idea to involve the Board or senior management in the operational matters of the office because they really don't know much about what research involves and they'd just hold everything up. I think high level reports, overall numbers etc would be appropriate (Survey 132, Regulator).

The impact of organisational cultures that focused on the local needs of the specific agencies

> It is intensely frustrating to have differing HREC processes. I find it astounding those sites are still requiring their own forms or even paper copies. We now just go to [Hospital] Health [HREC] and wait until the next committee meets rather than try the others (Survey 90, Applicant)

> My experience is that many hospital ethics and governance committees interpret the rules to develop their internal processes - this therefore differs from site to site and from state to state and makes completion of an application time consuming depending on the committee you are applying to (Survey 16, Applicant)

There were some suggestion that the complexity of the system involved leadership from all levels:

> Research managers, NHMRC and health depts responsible for state streamlined systems need to get together and sort this out (Survey 36, Applicant).

A coordinated leadership could then

> ensure consistency across research sites / ensure appropriate staff at each location of approval process chain /Promote discussions between all research groups (ethics, governance, site staff, sponsors) /Transparent sharing of metrics/performance (Survey 34, Regulator)

6.8.2 Standardisation

Respondents indicated the importance of standardisation in application forms, processes and roles.

> When sites have common processes so the processes are relatively the same in different sites. (Survey 47, Applicant)

Standardisation provided reliability and predictability. Predictability meant that the outlay of application resources could be planned which led to financial and human resource savings. For example, multi-site research applications usually involve formal arrangements between the different parties involved to clarity roles and responsibilities as well as outline any risk mitigation strategies. The assessment of individual research contracts can take time and resources, especially if legal counsel is required.

> Over the years, the initiatives that have been most effective are those that lead to shared experiences between sites - the CTRA [clinical trial research agreement available of the Medicines Australia website] is a classic. Before that each company had their own (if that) - mostly indecipherable nonsense that laid all the responsibility on the sites themselves (Survey 72, Regulator)

> LNR/ SSA [Site Specific Assessment Form associated with the Low Negligent Risk form] being the same sort of process as the NEAF/SSA [Site Specific Assessment Form associated with the National Ethics Application Form] is a good idea (Survey 77, Applicant)

Standardisation also applied to expectations and behaviour within the system.

> When the PI [principal investigator] or the CPI [coordinating principal investigator] know their responsibilities e.g. respond to emails/ requests in a timely manner (Survey 47, Applicant)

> An office checklist, for documentation provided and changes or additional requirements can be noted, an easy way to keep track of where you are at with a governance review (Survey 2, Regulator)

Several respondents identified the capacity of electronic research submission processes to change their practice.

> E submission will work really well - there's a few bugs but if we can work those out. Anything is better than photocopying 21 copies for an ethics review and then driving it through peak hour Melbourne traffic to get it submitted in time (Survey 81, Applicant)

> Electronic and a single hard copy initial submission has been helpful (Survey 80, Applicant)

Inconsistency in application forms and procedures also figured largely in respondents' beliefs of what prevented national system from functioning effectively.

> I have encountered difficulties with a HREC who would not accept a NEAF as the study I am involved in was deemed low risk by their organisation. I was instructed to submit a LNR form to our home ethics site before it could be accepted by the organisation as part of a SSA application. This additional time and paperwork created unnecessary delays in research (Survey 43, Applicant)

> Research Governance is not standardised. There are major hurdles due to the different jurisdictions, which, in my opinion, cause major delays (Survey 3, Regulator).

6.8.3 Communication

Some respondents highlighted the importance of communication to gain support for reform. However, at least one respondent indicated organisational will as more important in overcoming resistance to change

> In Victoria I appreciate initiatives such as VRGN [Victorian Research Governance Network] and REX [research Excellence], which core activities [are] to inform, train and standardise processes. At our institution we compare our processes to other similar institutions and adapt processes in order to minimise duplication. Communication, openness and motivation is key to efficiency (Survey 4, Regulator)

> Improved communication between researchers and ethics/governance office staff has led to significant improvement in approval timelines at our site [such as] improvement in the completeness/quality of documents submitted for review [and] improved approval timelines (Survey 28, Applicant).

Other respondents indicated frustration at any lack of communication.

> The hardest times are when new processes are introduced without consultation and vague responsibilities, no backup and unclear objectives. The new e-submission is a classic. Why DHS- why? (Survey 72, Applicant)

6.9 Summary

The chapter presented the results of the analyses of the Phase One survey which explored perceptions of the impact of the NMA on research governance practices in the Victorian public health sector. Descriptive statistics of the study variables, based on respondent role of Applicant or Regulator, were discussed. The distribution and frequency of survey responses was undertaken together with a comparison of the sample means using the Independent Samples t-test (or Student t-test) to determine any statistical evidence of significant differences in the associated population means. While responses to six items were significant, the remainder was not, indicating that there were other influences on respondent attitudes to the impact of the NMA.

Factor analysis was performed to identify the factor loading of the variables used in the survey. Regression analysis for the six constructs used in the study was performed to analyse the association among variables. The hypotheses were supported, in that coercive, mimetic and normative pressures were exerted by the NMA on research governance practices. However, analysis showed only partial support for the modifying impact of participant role as other demographics were identified as influential.

Thematic analysis of the qualitative responses in the survey detected three themes: leadership, standardisation and communication. Respondents expressed their requirement for consistency at all levels within the single ethical processes, the need for transparency between parties and their frustration at the lack of leadership, especially within their organisations. The findings from this chapter are discussed further in Chapter Eight.

CHAPTER SEVEN: PHASE TWO SEMI-STRUCTURED INTERVIEWS

7.1 Introduction

The aim of the Phase Two interviews was to develop a deeper and broader understanding of how public healthcare organisations engage with the National Mutual Acceptance (NMA) of single ethical review, a government initiative to the review of streamline multi-site research, and how this engagement is likely to progress into the future. Phase Two built on the findings from Phase One.

This chapter presents results of the interviews that formed the basis of Phase Two investigations and the qualitative analyses of the data. Chapter Seven is structured as follows. Section 7.2 describes the interview participants and Section 7.3 explains how participant consent and the semi-structured interview were undertaken. In Section 7.4 the analysis of the data leading to the development of themes is discussed. Section 7.5 explores the perceived authenticity of the NMA before examining the NMA as a coercive influence in Section 7.6; as a mimetic influence in Section 7.7; and as a normative influence in Section 7.8. In Section 7.9, interview findings on the future of the NMA are discussed. A summary of the Chapter is presented in Section 7.10.

7.2 Participants

Phase Two involved 21 semi-structured interviews with research "leaders" involved with multi-site research. Research leaders were defined broadly to include those who were actively involved in developing awareness of multi-site research and single ethical review. Thus, a participant who was employed in a non-managerial role could be influential through another mechanism such as a membership of a research interest group or an HREC. Potentially, the interview participants were a sub-group of the Phase One and in keeping with Phase One, participants were classified as Applicants and Regulators. Two of the participants noted that they were active researchers in addition to their employment role in regulation. A summary of the participants' demographics is provided in Table 7.1.

Table 7.1: Summary of interview participant demographics

Demographic	Classification	%	Freq.
Role	Researcher	19.0	4
	Researcher/regulator	9.5	2
	Regulator	71.4	15
Age	20-35	14.3	3
	36-50	42.9	9
	51-65	42.9	9
Gender	M	47.6	10
	F	52.4	11
Education	Post Graduate	19.0	4
	PhD	14.3	3
	Bachelor Degree	66.7	14
Level	Senior management	38.1	8
	Middle management	33.3	7
	Non-management	28.6	6
Years	Between 1 and 5	19.0	4
	Between 6 and 10	14.3	3
	Over 10 years	66.7	14

In contrast to Phase One respondents, the majority of interviewees were employed as Regulators rather than Applicants. Interview participants were recruited either through self-selection, invited by the researchers electronically through publically available email addresses or identified through third parties. The details of individual participants are presented in Table 7.2.

Table 7.2: Table of Interviewees

INT.	Role	Age	Gender	Education	Level	Years
1	Regulator (research director)	51-65	F	PhD	Senior management	Over 10 years
2	Regulator (HREC administrator)	20-35	F	Bachelor Degree	Non-management	Between 6 and 10
3	Regulator (Business manager)	20-35	M	Bachelor Degree	Middle management	Between 6 and 10
4	Researcher (trial coordinator)	20-35	F	Bachelor Degree	Non-management	Between 6 and 10
5	Regulator (HREC manager)	35-50	F	Bachelor Degree	Middle management	Over 10 years
6	Regulator (RGO)	35-50	M	Bachelor Degree	Middle management	Over 10 years
7	Researcher (trial coordinator)	51-65	F	Bachelor Degree	Middle management	Over 10 years
8	Regulator (HREC manager)	51-65	M	Bachelor Degree	Middle management	Over 10 years
9	Regulator (RGO)	35-50	F	Bachelor Degree	Non-management	Between 1 and 5
10	Regulator (HREC member)	35-50	M	Bachelor Degree	Non-management	Over 10 years
11	Regulator	35-50	M	PhD	Executive	Over 10 years
12	Researcher (ethics coordinator)	35-50	F	PhD	Non-management	Between 1 and 5
13	Regulator	51-65	F	Bachelor Degree	Executive	Over 10 years
14	Regulator (HREC manager)	35-50	M	Bachelor Degree	Middle management	Over 10 years
15	Regulator (Educator)	35-50	F	Bachelor Degree	Non-management	Over 10 years
16	Regulator	51-65	M	Post Grad	Executive	Over 10 years
17	Regulator	51-65	M	Bachelor Degree	Director	Between 1 and 5
18	Regulator/ researcher	35-50	F	Bachelor Degree	Manager	Between 1 and 5
19	Regulator	51-65	F	Post Grad	Senior management	Over 10 years
20	Regulator /researcher	51-65	M	Post Grad	Senior management	Over 10 years
21	Researcher	51-65	M	Post Grad	Senior Management	Over 10 years

7.3 Semi-structured interview

The interviews were conducted between 1 June and 30 September 2016. They were semi-structured, audio-taped and sequentially transcribed. A semi-structured interview is a qualitative method of inquiry that allows the researcher to follow-up avenues presented by the participant that might not otherwise have emerged. Phase One findings of a persistent uncertainty suggested that there was some non-compliance to the NMA guidelines and that these actions may impact diverse personnel in different ways. Semi-structured interviews were employed for this study in anticipation that, in conjunction with the researcher's pre-existing knowledge and experience in the research governance sector, this interviewing technique would allow an innovative illumination of the area under study.

The semi-structured interview used for this study combined a pre-determined set of open questions that were intended to prompt discussion (Appendix L) with the opportunity for the interviewer to further explore particular themes or responses. The interview schedule used for Phase Two included three main questions:

- What is your understanding of the National Mutual Acceptance (NMA) or the national model of single ethical review of multi-site clinical trials?
- What do you see as the enabler/barriers to a national single ethical review/ streamlined process?
- What is the future of the NMA of single ethical review?

7.3.1 Participant information and consent form

A copy of the participant information sheet and consent form was emailed to potential participants as soon as they had expressed interest in being interviewed (Appendix J and K). Written informed consent was obtained prior to each interview. Participants were interviewed on one occasion only. Interviews ranged from 30 to 75 minutes, and participants were allowed as much time as necessary to respond to each interview question.

7.3.2 Privacy and confidentiality

Several measures were used to ensure the confidentiality of the participants. Interviews were transcribed by the researcher rather than a third person. The transcripts were de-identified by the researcher and only de-identified data was made available for analysis. A pseudonym was allocated to the transcripts and used in any reference to the participant in the thesis. Prior to the interview being accepted for analysis, interviewees were emailed their transcript with a request that they vouched for the accuracy of the data. During the study, physical data was securely stored in a locked filing cabinet and electronic files were stored on a password protected computer. At the completion of the project, the data will be retained for five years before being destroyed, as per Victoria University's *Research Data and Materials Plan* (RDMP). The minimum retention period is normally five (5) years.

7.4 Analysis of the data

Analysis of the data was conducted in accordance with the methods outlined in Chapter Five to reduce the narrative to the core experience that reflected the narrator's account of how the NMA impacted research governance practices.

Data was reduced to: Recognition of the NMA; Coercive pressure from the NMA; Mimetic pressure from the NMA; Normative pressure from the NMA; and the future of the NMA. Coding within each section identified important features of the participants' experience of the NMA. These codes were analysed in conjunction with the conceptual model and relevant literature, to create themes. Any similar themes were combined under a representative main theme. Table 7.4 lists the sections, themes and sub-themes through which analysis of the data is presented, after which a discussion of the thematic analysis is presented.

Table 7.3: Summary of the themes and sub-themes

Section	Main theme	Sub-themes
Recognition of the NMA	Validity of the NMA infrastructure	Research as a core activity
		Perceived authenticity of the NMA
		Synchronisation with the culture of research review held by healthcare agencies
Coercive pressure from the NMA	Importance of leadership	The role of government
		The role of organisational leaders
	Inconsistencies in the NMA weaken its coercive pressure	Local versus central
		The problems of being downstream
		Change management is more than technical adjustment
	Need for a single research authority	
Mimetic pressure from the NMA	Opportunity and mimetic pressure	The importance of networking
		Mimetic pressures were not always viewed favourably
Normative pressure from the NMA	Lack of a professional recognition	
	Research governance credentials were unclear	
The future of the NMA	A sustainable future system requires consistency	
	The NMA as a future coercive influence	One system, one central authority
		Disengagement of the HRECs from agencies
		The need to engage the whole agency
		Metrics that reflected the scope of site governance
	The NMA is a weak future mimetic influence	
	Future normative influence is not clear	Strengthened knowledge base
		The need for professional networks
		A voice for all

7.5 Recognition of the National Mutual Acceptance (NMA)

Phase One examined the importance of research in public healthcare agencies by exploring the degree to which research was considered a core activity. The findings from Phase One revealed an expectation among survey respondents that research should be recognised by healthcare agencies, but there was a diversity of opinion as to how this recognition should be formalised. From these findings, it was surmised that participating in multi-site research and the associated requirements of the NMA, such as the emphasis on speed and the need to rely on others to complete the process, might also

challenge healthcare agencies. Phase Two then examined how the NMA was perceived. The first question of the interview asked participants about their understanding of the National Mutual Acceptance (NMA) or the national model of streamlined research review and whether their understanding had been achieved. Interviewees were asked to describe their expectation of the NMA and how they saw the NMA evolving into the future.

Within this section, the main theme was the validity of the NMA infrastructure was supported by several sub-themes.

7.5.1 Validity of the NMA infrastructure

The NMA was generally recognised in principle as a valid process for managing multi-site research. There was an acceptance that "the National Mutual Acceptance scheme is here and it's here to stay" (Interview 6) and that it is "a good system in principle" (Interview 17). However, this recognition was qualified by participants' experiences of working with single ethical review and how they felt research was regarded which were sometimes problematic. There are "many roadblocks along the way from the submission point of view" (Interview 17).

7.5.1.1 Research is a core activity. Concerns about how research was regarded emerged in the interviews. Participants indicated that the major focus of healthcare agencies was clinical care and that the "high level of specialisation" (Interview 17) required for involvement in research prohibited senior management and the Board from understanding the complexities of the research support structure. -

These concerns suggest two things. Firstly, if there is limited Board engagement, then there will be difficulty in structuring a research strategy that describes the governance requirements. Secondly, a lack of research structure will impact on how the agency as a whole perceives the authenticity of the NMA.

7.5.1.2 Perceived authenticity of the NMA. In general, interviewees expected that the benefits of being involved with the NMA should outweigh any burden. They anticipated

that multi-site research reviewed through the NMA should undergo a more timely ethical review than if each site involved undertook individual HREC assessments.

> It should be one single ethical review that expedites the commencement of a study. While that ethical review is happening the investigator can be seeking governance approval at their local site. It really should mean that it's a faster process (Interview 5).

One anticipated benefit of the NMA system is of greater efficiency. NMA guidelines describe how ethics review is conducted by any accredited HREC within any participating jurisdiction and should be completed within the 60 day benchmark[11], implying that the quality of the ethics review remains constant across the different committees. At the same time as the ethics review is undertaken, individual site specific assessments are conducted so that both ethics and site decisions occur simultaneously.

> Two things – firstly that it is a streamlined system; that the system of research review is faster than before, with no loss of efficiency but secondly that it is invisible (Interview 17).

Standardisation was perceived as the backbone of single ethical review. The basic tenet is that although researchers apply to different HRECs and different healthcare agencies, the same application processes are employed. In this model, the individual requirements of the healthcare agency are invisible to the researchers. However, interviewees indicated that the main difficulty with the NMA was that individual idiosyncrasies are found at institutional and state levels. They noted inconsistencies between the requirements of individual HRECs and for specific site governance processes.

> I think the biggest issue is the lack of consistency across Australia, in terms of the forms that are used, the review process and the approval letters. If there was consistency across the states, everyone on the same page, same regulations, that's the ideal scenario (Interview 12)

[11] A 60 calendar day benchmark for performance of ethics review has been set for a 30 working day benchmark for performance of ethics review has been set in Victoria (Department of Health & Human Services, 2015)

There were other concerns that HRECs were not adequately prepared to undertake inter-jurisdictional reviews (Interviews 5, 8 and 9).

Inconsistency is perceived as a substantial burden to research applicants. Rather than assume application guidelines apply at a given HREC, participants who had application experience stated that they were first required to determine any specific requirements such as additional hard or soft copies. Most agencies required additional processes to the online system, which has often led to the perception that the dedicated IT system, discussed later in this chapter, was extraneous to the research office's own processes. The system was observed by respondents to be inefficient and not used to its full extent. Often, this lead to data entered into the system outside the expected sequences so that, for example, the time between events did not match what actually occurred.

The users of the IT system viewed data retrieval as problematic. They were unable to readily retrieve data that they required.

> There is a disconnection from the information. We can't search the system to find that information that we need to manage our trials. We can't get the metrics (Interview 11)

7.5.1.3 Synchronisation with the culture of research review held by healthcare agencies. The NMA is a "top down" approach. The governments, Federal, State and Territory, have played a central role in its introduction but the activity of single ethical review is performed by the healthcare agencies. Respondents observed that healthcare agencies usually had their own approach to research review and commented on the tensions between the NMA requirements and those of their own agency. This tension was compounded by a lack of accountability or performance measures for research administration.

> It's not part of the CEO's KPIs [Key Performance Indicators]. It's not part of the logistics of the hospital. They still see research as a nuisance, an extra, not part of the standard care (Interview 7).

Some participants felt the scope of the NMA, which focussed only on the applications for ethical and site specific review, was too limited. It was observed that, historically, research governance timelines related only to the ethics/ governance processes but in actuality, covers a far broader span as indicated by the NHMRC *Good Practice Project* (National Health and Medical Research Council, 2016a). These participants described their view of research governance of a commercially sponsored clinical trial as starting with the first contact from the commercial company. Managing the project timelines effectively meant that research organisations should be aware of checkpoints such as the time between the feasibility assessment, one of the first steps in clinical trial conduct, and formal notification that the study site is accepted into the trial. Processes outside the ethics approval or RGO authorisations are important for the agency to act on (Interview 3).

Other participants felt the decisions made by the accredited HRECs were often not the same or of sufficient standard as their own processes. For example, they described lack of clarity around whether the centralised ethics committee had reviewed all the provided documentation. This was especially problematic when a review was undertaken by an HREC from another state that had different legislative requirements. They described the design of the dedicated IT system as having to "serve metrics and … not serving efficiency" (Interview 6).

Another example of tension was where the NMA requirements contradicted the agency. Electronic signatures, a central tenet of the dedicated IT system, were not always accepted by the agency.

> We get a hard copy of the signatures. Even though it's electronic for submission, we still require the hard copy signatures to come to us …This organisation does not accept electronic signatures for documents at that level (Interview 8).

In situations where electronic signatures were accepted, research offices did not enforce use of the electronic authorisation undertaken through the dedicated IT system.

> To be honest, I don't know – they accept scanned signatures … I'm not sure … I just get these things, sign it and scan it and send it in. It's easier for me to do it that way (Interview16).

These observations suggest that there is a lack of consistency in how the NMA is regarded by different stakeholders. Literature indicates that an emphasis on local or organisational needs is problematic when addressing the goals of a national system (Franck et al., 2004). While this finding is discussed further in Chapter Eight, the significance of such ambiguity impacted on the development of all the other themes.

7.6 Coercive pressure from the NMA

Within Institutional Isomorphic theory, coercive forces are the external pressures exerted by government, regulatory, or other agencies to compel another institution to behave in a certain way. The government is able to exert pressure on public healthcare agencies undertaking multi-site research to participate in the NMA approach to single ethical review. This suggests that organisational adoption of the NMA is a managed process, that management and service personnel could understand the scope of the project and there are clear reporting lines to the organisation and government. However, while the NMA has introduced a change in the way ethical review of multi-site research is managed within the public health sector, participants varied in their perception of the NMA coercive pressures.

7.6.1 Importance of leadership

The role and importance of leadership was highlighted in this study. If the introduction of the NMA was to be successful, then it was conditional on effective leadership at all levels, along with continuity of that leadership in sustaining momentum.

7.6.1.1 The role of government. Government strategy is integral to the public sector. Typically, interview participants acknowledged the authority of the government to introduce the NMA into the public health sector and that this change was established (Interviews 6 and 7). Other participants expressed support for the NMA such as, "the good thing about the National Mutual Acceptance [NMA] is that you've got the approval from the government to do it. That authority to do this has been great"

(Interview 1). These comments implied that introduction of a single ethical review was inevitable, in order to expedite the numbers of ethics reviews required for multi-site research, but it also aligned with healthcare agency choice.

Participants also looked to the government for establishing consistency of the system. Public healthcare agencies are expected to conform to guidance provided by the Department of Health and Human Services (DHHS). For example, standard operating procedures (SOPS) outlined the roles and tasks of different personnel and how applications for research review were made through a dedicated IT system. Typically participants remarked on the importance of uniformity because "we are looking for standardisation. We accept certain measures are required*"* (Interview 9). Participants also noted the importance of consistency between similar processes, as indicated by "I think the other thing that's doing it is the standardisation of forms" (Interview 16). Consequently, all participants indicated a high familiarity with the NMA procedures.

However, there were also indications of misalignment between government and organisational objectives. This was evident in the responses to performance reports created by the state government from the dedicated IT system and provided to agencies. For the government, key performance measures related to the overall time of approval for all research sites, however the agencies' view of success related only to their own performance.

> One of the problems I have, looking at what come from above, our CEO gets a report on our turnaround time. He says why this is taking you 280 days to do this. I say it doesn't take us 280 days. It took 6 days. But the 280 started when someone identified us as a site for the trial. So the central system put that down as when the clock starts clicking so it looked like 280 days before we had signoff (Interview 11).

7.6.1.2 The role of organisational leaders. Organisational leadership was identified as a critical factor in both the adoption and ongoing momentum of the acceptance of the NMA. The CEO was perceived as the strongest driver of research awareness. In the

following excerpt, a participant explained that the process of bringing research to the attention of the Board began with the CEO.

> Our board is very, very, very supportive of research. There are two reasons for that. Firstly our CEO has a long history of academia …So that's in his blood. Plus there are people on the board who are also researchers, so he will support research through and through until the cows come home (Interview 16).

It was perceived that the NMA and single ethical review are not well understood at senior management and Board level. Administrative reports regarding research activity were generally confined to "hard" governance measures, such as numbers of clinical trials undertaken at that agency. Differentiation of single site or multi-site research was not emphasised.

> At a higher level, they get muddled up between what's ethics and what's governance. They find that conceptually difficult. They see it as a labyrinth … they wouldn't know the level of detail and I wouldn't expect them to… So we do report regularly, but to be honest, unless you're in it you wouldn't really understand the complexity of it all (Interview 5).

Participants identified that senior managements lacked understanding of the NMA requirements.

> Even though research has come a long way in the last 30 or so years, those above us are not aware … to be involved in research, as a researcher or as a committee member or in a research office, that's a high level of specialisation. The average board member wouldn't make such decisions. That's not to say they wouldn't in the future. (Interview 17).

It was observed that limited support from senior management meant that research administration requirements were not given priority. In particular, there were delays of

research administration processes, such as timely endorsements from relevant department managers, because "in this current system there is no requirement to commit" (Interview 1).

Timeliness is the central tenet of the NMA. Participants argued that an organisation undertaking multi-site research "should be aware of its research obligations just as much as the clinical roles. It should be part of the hospital accreditation process" (Interview 7). There was a suggestion that "it would be awesome if we could put time to start up on the CEO's performance [in relation to timeliness of research authorisations]. That would work" (Interview 7) but this led to further reflection on the role of a research authority. The need for an authority able to compel standardisation across relevant stakeholders was raised in many interviews.

Research leadership was also led from a participant's professional capacity, such as their breadth of experience. A senior regulator, who was also a member of an HREC, remarked that:

> We've been in situations where we've thought "that participant information is not good. We wouldn't have approved it" but we've let it go through. It's not ideal but it's probably good enough. So in the spirit of the NMA, we'll just let that go through. And I think that everyone else is doing that as well (Interview 16)

7.6.2 Inconsistencies in the NMA weaken its coercive pressure

The strongest challenge to the coercive influence of the NMA came from organisational adaption of the centralised framework to meet local needs. In Victoria, each healthcare agency is a distinct legal entity and must demonstrate to the state government that it had met its specific clinical and financial obligations in accordance with approved strategy. While each healthcare agency had agreed to participate in the NMA through memos of understanding with the state government, this agreement was not exclusive of other decisions. Some agencies required additional information to the data collection specified by the NMA in order to manage risks in accordance with their internal governance demands. The addition of local requirements outside expected NMA

procedures had a profound impact on research applicants and on any downstream or accepting organisations. A number of sub-themes emerged from the interviews: local versus central; NMA not recognised by higher levels in the organisation; the problems of being a participating or an accepting site; change management is more than technical adjustment and the limitations and impracticalities of the dedicated IT platform. These sub-themes indicate the complexity of determining the coercive pressure of the NMA.

7.6.2.1 Local versus central. Centralisation introduced economy of scale into the review of research. It was anticipated that use of a dedicated process, whose only role was to undertake an ethics review, would minimise the bureaucratic load on healthcare organisations. Hence, central or accredited HRECs have full autonomy over the ethical and scientific acceptability of a project, while each participating site was responsible only for deciding its capacity to undertake the project. In Victoria, there are seven accredited HRECS which are associated with Alfred Health; Austin Health; Melbourne Health; Peter MacCallum Cancer Centre; The Royal Children's Hospital; Monash Health and St Vincent's Hospital (Melbourne). In order to function as a cohesive process, the NMA model assumes homogeneity; that the ethics committees were similar to other ethics committees and the individual sites were similar to their peers. The supporting standard operating procedures generated by the state government also assume consistency and that the same processes occur at each site.

Participants, however, observed that "different institutions have … different issues, different expectations, different funding models, different boards, different staff - all that sort of thing" (Interview 1). Some respondents expressed concern on how the NMA impacted on their practices. They observed that "it was assumed that the big guys in town are the best, but this is not necessarily so. In fact it's not been our experience" (Interview 4). They indicted there were many factors in accepting a decision from an HREC based outside their own organisation. It was perceived that each HREC, all of which were based within an organisation, developed practices according to their parent administration so "that's my frustration of having different HRECs reviewing … every HREC is different" (Interview 4).

Differing organisational risk appetites meant that individual organisations had a different approach to "how they do governance and what they think is important"

(Interview1). Organisational risk appetites can be defined as the amount and type of risk that an organisation is willing to absorb in order to meet their strategic objectives. Risk appetites differ depending on an organisation's sector, culture and objectives (Institute of Risk Management, 2018).

Regulators acknowledged that local needs were prioritised over the NMA requirements and that different practices were occurring. For example, conditions in the research offices varied and they felt it was not always possible to adhere to the guidelines.

> Sometimes you think there's not the staff or resources to do it in the way we are supposed to. It's much better to do certain things the way that suits you. You can't stick to guidelines if it doesn't work (Interview 6).

There was suggestion that the only way research governance could be fully standardised across organisations was if "the government paid for everything and hospitals didn't have to worry about costs or credentialing or anything" (Interview 1).

A profound contributor to the focus on local rather than system needs, was that the NMA was not recognised by senior management. Participants revealed concerns that research was not generally considered core business in public healthcare organisations. They described a lack of organisational dedication to timeliness of streamlined review because "in this current system there is no requirement to commit" (Interview 1), although an organisation undertaking research "should be aware of its research obligations just as much as the clinical roles. It should be part of the hospital accreditation process" (Interview 7). In particular lack of organisational recognition of the NMA impeded internal processes such as timely endorsements from relevant department heads. The need for an external research authority able to compel standardisation across relevant stakeholders was raised by many participants.

7.6.2.3 The problems of being downstream. The NMA was initially introduced in response to concerns that overly bureaucratic and duplicative review processes involved in the approval of multi-site research jeopardised timely and efficient research start-up. A fundamental tenet of the NMA is harmonisation; that application requirements for

single ethical review are consistent, involve equitable processes and that the outcome of the ethical review is provided to all accepting or participating sites within a predictable timeline. In principle, the ethics decision is made available to all sites simultaneously.

> But we know that there's enormous holdups because we are downstream; we rely on other people to do things so we're not in charge of our own destiny. We are always reliant on other people to do the right thing and that holds things up at our site enormously (Interview 19)

A participating or accepting site is one that agrees to accept the ethical and scientific review of a reviewing HREC and not undertake any further review by the organisation's HREC. At the same time, a participating site must agree to conduct a site specific assessment (SSA) as part of an institution's research governance responsibilities (Department of Health & Human Services, 2015). As both ethics approval and site authorisation are required before a project can commence, the process relies on synchronisation between ethics and site governance.

Consequently, diverse local practices of individual HRECs were found to be problematic. In particular, participants who had experience of applying for ethical review observed that use of local forms, specific to an individual organisation, contributed significantly to application burden, as shown in the following quote:

> … I was told by the CAS [Central Allocation System] office that we only needed to do an electronic submission … But no, we had to provide two hard copies and a USB by that same time for it to be a valid submission. … So it's the logistics and the differences in the HREC requirements for submission (Interview 4).

Both Applicant and Regulator participants complained "a lot of inconsistency" (Interview 12) as well as "a big list of things that the governance officer requires to do a formal submission" (Interview 4).

Lack of harmonisation also impacted the Regulator group who explained how interjurisdictional differences impeded their own research offices.

> When I think of what is wrong with the system, I would like more standardisation. I see that there is a lot of work towards standardisation already but we are not there yet. I understand that there are different jurisdictions that can cause a lot of issues (Interview 9).

Regulators observed that HRECs tended to undertake scientific and ethical reviews within the regulatory and legal frameworks of their own states and did not always consider the frameworks of other states. Although the ethics review in itself is not law, its considerations are encased in the laws pertaining to that community to which its decision will apply. As described in earlier chapters, the regulatory and legal frameworks of individual jurisdictions may differ so that the reviewing HREC and the regulators needed to be aware of any legislation and regulation that might impact the undertaking of a research project. This awareness or lack thereof "will mean that it will have a flow on effect to the sites because if you [the HREC] approves things without being aware of those difference, it actually makes it a nightmare" (Interview 5).

Concerns were raised in regard to the Victorian Specific Module (VSM) in particular. It is a mandatory requirement of the Victorian government that this form is submitted to the reviewing HREC of any project involving a Victorian site. The form is designed to address relevant Victorian legislation such as that regarding use of ionizing radiation for research purposes. As the *Radiation Act 2005(*Vic) (AustlII.) applied only to this state, participants observed that "…no other states requires this or looks at it" (Interview 8) and when the interstate HRECs were requested to include the VSM in their considerations "they just don't want to talk about it. It's not important to them" (Interview 11).

Deviation from expected procedures could result in substantive delays. For example HRECs did not always follow the standard templates in their approval letters and a requests for re-issue of the HREC approval letter was required.

> We waited one month for a reviewed letter from [an interstate HREC] … The approval letter was given but they didn't list some of the items. It went back to their research office to request that they rewrite the letter, including the missing items (Interview 7).

Site authorisation could not proceed until it was clearly stated what the HREC had approved. The alacrity of which the letter was re-issued varied.

> It's a simple query that could have been resolved within days but they are not responding. This issue has now been escalated to senior management for resolution. These are the issues that de-rail governance and timeliness hugely (Interview 9).

Applicants were not unsympathetic to the workload of the HRECs and their associated offices but they raised concerns that appreciation of interjurisdictional review was not yet embedded.

> When we request an updated letter, they often reply that we are the only site with this request, but we might be the only Victorian institution involved (Interview 8).

They indicated that lack of harmonisation impacted greatly on their own practices.

> I don't believe that the streamlined review is helping us to reach our end targets. If I'm given the opportunity to do a single site submission, I do (Interview 7).

7.6.2.4 Change management is more than technical adjustment. Although use of the dedicated IT system was required, participants indicated that use alternate application processes were common and had become entrenched into the day to day operations of the research administration offices. Entrenched behaviours provide a beneficial social structure within an organisation, such as providing the rules around how interdepartmental communication is managed. The implications of entrenched behaviours is that they are likely to endure and resist pressure for change (Zeitz , Mittal,

& McAulay, 1999). It also implies that such behaviours are organisationally specific, developed to meet the needs of the individual organisation.

Shortly before data collection commenced for this project, a change occurred. On 19 June 2015, the Victorian Department of Health and Human Services introduced "e-submissions", an additional functionality through which a research application was submitted electronically from the researcher's account in the dedicated IT system to the research administration office of their choice. This increased functionality also required the research administration office staff to engage more frequently with the system. In technical terms, the changes introduced in e-submission appeared as a logical extension of the previous system. Information and training sessions on e-submissions were provided prior to the implementation (Department of Health and Human Services, 2015). However, the changes impacted on the individual agency's practice variations in unexpected ways, leading to user frustration.

> It's been difficult as well working with [the dedicated IT system] mostly because people don't understand why they're doing it and what it means. The Helpline is good but e-submissions has been an absolute nightmare. I don't even know what to say about that, but that's probably been the hardest thing recently (Interview 2).

The limitations and impracticalities of the dedicated IT platform were also highlighted in the interviews. Regulator interviewees expressed frustrations at the limitations and impracticalities of the dedicated IT platform they were required to use to manage research applications. Although all participants acknowledged that they used the system, none of the regulators interviewed relied on the system and each research office had retained alternative practices. Typically, those from the Regulator group identified process issues.

> I'm using a database that is not providing any efficiency gains whatsoever… It's slow … I take shortcuts when I need to … So that's the biggest issue that we have. The system is to serve metrics and it's not serving efficiency (Interview 5).

> I wouldn't pretend there is confidence in [dedicated IT system]… [It] is only there because we have to … If [dedicated IT system] was a good database, we would use it. But it's slow, it's cumbersome and appalling (Interview 8).

> We've got the [dedicated IT system] in there which is keeping a track on the data, although unfortunately that data is very inaccurate (Interview 16).

> We want people to provide electronic and hard copies to us. We're not going to waste our time downloading documents, we don't have the time (Interview 6).

Regular reports were provided by the Department of Health and Human Services to the Chief Executive Officers of participating healthcare organisations listing the ethics and governance approval times. Despite these reports being drawn from the data within the dedicated IT system, Regulatory participants declared that the metrics being reported were not correct. They stated that "nobody believes those reports when they come out from the DHHS, they just look at them and go "fiction" and put it in the bin" (Interview 5) and that "I haven't got the time to worry about that. My CEO understands that, as do most CEO's, that the reports they get from the health department they just chuck them straight in the shredder" (Interview 1).

Some participants indicated that they had developed their own reporting processes, either as well as or in place of the official data collection:

> First of all we run a spreadsheet for [the single ethical review] activities so we have an understanding of what's happening. That's also where we get our time measures from: submission, review and approval dates. We have no confidence in [the dedicated IT system] data. (Interview 8).

> But in [the dedicated IT system] you have to print 3 reports to get what you want, every date entry prints out on a different line, and they

> don’t print out altogether. Who can be bothered trying to synthesise that when I can do it like that (*snaps fingers*) somewhere else. There is absolutely no carrot at all, just bricks to weigh me down when running reporting from [the dedicated IT system] compared to what else I have (Interview 1).

Some of the healthcare agencies were currently participating in a NHMRC scheme , the Good Practice project, which aimed at identifying principles and critical success factors involved in site assessment and site authorisation (National Health and Medical Research Council, 2016a). The project identified the importance of a site undertaking pre-emptive activity before contact was made by a company or research sponsor intending on inviting that site to take part in a clinical trial. Participants expressed concern that the dedicated IT system, and consequent data retrieval, was based on a belief that important timelines relate primarily to the ethics and governance processes, whereas “… in actuality [governance] covers a far broader span, as indicated by the NHMRC Good Practice project” (Interview 3).

7.6.3 Need for a single research authority

Typically, interviews identified the need for an authority that was able to enforce a consistent system, but the role of a central authority was envisaged by the researchers and regulators differently. Regulator personnel focussed on the need for cohesive practices between the government and their own practice needs, whereas researchers identified the need for an authority to constrain any divergent application processes.

One example raised by a Regulator participant referred to the disconnection between the dedicated IT system data collection and the data required to complete HREC activity for the NHMRC annual report. As a condition of HREC registration, the NHMRC requests annual reports the HRECs’ activities over the preceding calendar year (National Health and Medical Research Council, 2017). While the NHMRC requires certified institutions to submit an annual report regarding multi-site reviews conducted by an HREC, neither the National Ethics Applicati0n Form (NEAF) nor the Victorian Low or Negligible Risk (LNR Vic) application forms collected the data so that staff had to resort to their own in-house databases (Interview 2). It was felt that regulator staff need “a coordinating

body that works with you to improve things rather than talk from a business side of things" (Interview 2).

Whether an overall body of authority could be drawn from existing resources was also raised. There was a suggestion that the authority of the National Health and Medical Research Council (NHMRC) could be expanded as

> … the NHMRC collates all the regulation regarding research … the application form, the conduct of research, the National Statement – that's the NHMRC so why shouldn't the NHMRC be the one to have the authority? (Interview 9).

However, other participants noted that the central research body required the authority to impose upon the individual states and territories. Although the NHMRC is "central to research review … it does not have dominion over the states" (Interview10) but, concurrently, the control of the state governments is limited to the public sector as "private institutions can choose to play ball or not" (Interview 1).

7.6.4 Summary of the NMA as a coercive influence

In principle, the NMA provides a coercive influence in the public health sector, through government MOU's and guidance on how single ethical review and site governance are managed. Interviews indicated a high level of conformity to the formal processes of the NMA, but they also indicated limitations to full engagement with the NMA. In particular, tension was noted between the requirements of the NMA processes and the local needs and customs of the individual public healthcare agencies.

Although government support acted as a coercive pressure for acceptance of the NMA, the interviews indicated the complexity of the change. Three themes emerged about the impact of the NMA in providing coercive pressures: "The importance of leadership"; "Inconsistencies in the NMA weaken its coercive pressure"; and "Need for a single research authority".

7.7 Mimetic pressure from the NMA

Institutional theory proposes that organisations are inclined to model their practices on other organisations which they deem to be successful or legitimate in a specific sphere and that this mimicry is stronger in times of uncertainty. This is referred to as Mimetic Isomorphism and involves decision-makers deliberately making an effort to obtain information about other organisations in order to imitate them (Villadsen et al., 2010). Indication of mimetic isomorphism may be found in standardised structures or program formats or in common expressions or symbols (Frumkin & Galaskiewicz, 2004). Hence, mimetic influence is affected by an intentional action, in contrast to coercive and normative isomorphism where the influence originates outside the organisation.

Mimetic behaviours can develop at any level within an organisations when an organisation's goals or means of achieving these goals is unclear and copying others is perceived as a safe way to proceed.

7.7.1 Opportunity and mimetic pressure

7.7.1.1 The importance of networking. Networking, information forums and formal meeting between similar personnel roles were acknowledged as mechanism through which people could learn about other practices and share ideas. These opportunities were particularly welcomed by those participants employed in the research administration offices.

In addition to providing a chance to learn, networking provided an opportunity to share knowledge and debate critical issues where the action was not clear. These events allowed managing personnel to deliberately plan to seek out the knowledge of others regarding appropriate action.

> Whenever you've got a study that involves certain issues, you can ask whether other sites would do those procedures or how invasive would a procedure be regarded (Interview 5).

These comments indicate that networking provides opportunity for mimetic pressure to develop. It also indicates the occurrence of mimetic pressures at the level of individual decision-makers.

Interview findings suggested that limited settings are more conducive to the development of mimetic pressures. Some organisations had created their own local networks or groups. The intention of these bodies was to remain within the NMA framework, but to expedite processes through a small group of those people who are "active at the coal face and who is driving it and working in that space in order to expedite processes and to understand what makes it better" (Interview 18). Participants indicated that the roles and responsibilities of the group members were formalised through written agreements and the groups focused on specific targets, such as commonality of processes between the member sites.

> [We] undertook a mapping process, reviewed all the documents from the member sites and orchestrated consensus on common template for HREC approval. Also developed key performance indicators (KPI) such as time to send letters out and times to response (Interview 18).

Findings indicated that mimetic factors were more influential within limited environments, such as a small group of members. The following quote related to a group of research administration personnel who met regularly to discuss their different site practices.

> If someone has a good idea that works for them, and others can see that, it may be adopted by others … If [two large research centres] are adopting this, my organisation is prepared to just use their template, subject to our legal team's advice. Thus you already have three institutions that agree on the same practice. Other institutions will adopt that as well (Interview 9).

Smaller groups were able to detect more immediate goals, such as development of a research contract for a trial that many of the members were participating in and they were also able to see the immediate impact of any change efforts.

7.7.2 Mimetic pressures were not always viewed favourably

Mimetic pressures were not always viewed in a positive light. Typically, participants referred to the importance of consistency in undertaking the NMA and that different parties undertook their tasks as per the guidance provided by the DHHS.

> I don't want people to be doing random things outside the agreed system. The agreed system is the basis of what we are doing (Interview 20).

> So during those conversations your colleagues would say "oh by the way, in NSW this happens or QLD, we don't worry about that but we do this instead". A lot of this is learn as you go, which isn't a bad thing but it's not necessarily promoting a good, consistent, robust system (Interview 5).

Literature suggests that mimetic pressures can develop in contrast to the expected direction. In one case, a participant described how a recent introduction of new form, not included in the NMA forms, at multiple sites delayed multi-site research approvals. Until recently, financial agreements had pertained only to larger studies or those where finance or other resources were involved. More recently, such agreements have been introduced for multi-site low-risk projects, where no money or resource exchange was involved.

> What's really driving me nuts … is the need for research collaboration agreements. We never used to have these, unless there was a big multi-site study where a whole lot of money was changing hands … I don't know who's initiated this but it's happening at all the major hospitals … I honestly don't know how it has come about. … I haven't seen NHMRC saying that we have to use these agreements. (Interview 16).

The implication from this comments was that the mimetic impact was problematic because it influenced a change for the benefit of one group but that was detrimental to another.

7.7.3 Summary of the NMA as a mimetic influence

Two themes emerge from analysis of the mimetic influence of the NMA: "Opportunity and mimetic pressure" and "Mimetic pressures were not always viewed favourably". Interview participants indicated there was significant uncertainty around meeting NMA requirements. According to literature, uncertainty promotes mimetic behaviours because copying a successful peer conserves resources and is a safe way to proceed (DiMaggio & Powell, 1983). However, participants noted that mimetic behaviour intending to address a problem at organisational level may present challenges to national goals. This is also consistent with findings from the literature (Franck et al., 2004).

A significant issue identified by participants was that more senior levels in organisations participating in the NMA may have less understanding of the bureaucratic processes around research governance. Thus, mimetic decision-making may be originating at less senior levels which have led to changes that may benefit one group at the expense of another.

In the current environment, participants in general supported the opportunity for governance personnel to liaise and discuss practices. However, when participants discussed the future of the NMA, they felt that changes of behaviour at an organisational level would be counter-productive to a national system. This finding supports previous findings in literature and is discussed further in Chapter Eight.

7.8 Normative pressure from the NMA

Normative pressures result as a consequence of social influence leading to conformity within a specific organisational field, such as professional standards, education and hiring staff from a peer organisation. These activities pressure an organisation to behave in accordance with external norms and values.

Phase One findings indicated that the survey respondents regarded professional standards in research governance as important, but there was a degree of uncertainty as to whether current standards existed. In the second phase of data collection, participants' perception of the NMA as a normative influence identified the lack of professional recognition and the need for education as issues.

7.8.1 Lack of a professional recognition

Professional standards are an important source of guidance of the preparation, support and development of a specific role. Historically, the roles within research offices have been mainly defined by the employing organisation. When the single ethical review was first introduced participating public healthcare agencies were required to create a new role, the Research Governance Officer (RGO). However, there was no single position description and so each organisation regarded the role within its own local context leading to a variety of responsibilities of the same title in different organisations.

Typically participants acknowledged that lack of clear professional recognition for research governance staff was problematic. In some organisations, the RGO role was quite senior and able to provide decisions, whereas in other organisations the same role was required to refer similar issues to a line manager. There was no specific certification required for these role.

> Those are the inconsistencies. We don't have a common understanding of the process, we don't have a common standard of what's acceptable (Interview 8).

> The first thing I did when I started was to ask for a manual of what I am supposed to do. I asked my manager. He said that there isn't a manual for the RGO role (Interview 9).

Some participants observed that the lack of professional recognition of research governance roles stemmed from research not being included in the "core" business of the organisation. Core business refers to an organisation's main or essential activity. The success of core business depends not only on how well individual department

perform, but also on how well that activity integrates with other organisational activities. The timeliness of research approvals, for example, involves not only the researchers undertaking the research, but all of those personnel who are endorsing or "signing off" the project. Participants observed that signing off was often delayed, which impacted on start–up times.

> We have to get heads of departments to sign off our site assessments. It can sit there for two weeks because its "only research". They can make it quite difficult for us. The CEO is not saying to these heads "get these forms done quickly because it's really important" (Interview 7).

Within a public health organisation, core business activities are also reported to the current state Minister for Health. Consequently if clinical trials activity are not part of the hospital's reporting requirements to government, then "… I think that's a fundamental problem … I think that's a key road block" (Interview 12) and "I don't think that they [public health organisations] are aware of research's role in patient health" (Interview 7).

7.8.2 Research governance credentials are unclear

It was difficult for participants to define what credentials were required to work successfully in research governance. A credential is a measure used to indicate suitability for a role, such as an educational achievement, competence, or authority issued to an individual by a third party, that should allow employers an understanding of the capacity of the worker. Formal credentials may not, however, provide assurance that a possible employee had attributes required to work in the role, such as, attention to detail or problem solving. When participants reflected on the credentials or education required to work in research governance they had a variety of interpretations. Different points of view included:

> I don't think that formal education is what makes the difference. It's the interest in the field that helps them understand why we are doing

> what we are doing. So some sort of qualification that indicates interest is a good thing but not absolutely vital. (Interview 13).

> The best way to learn is to be put in that environment and work with people who do a good job. That's the best training. Now that could be part of a course, a structured internship program (Interview 1).

Professionalism is generally considered more than the skill or good judgment expected from a person who is trained to do a job. It is also implied in the growth of the employee in an organisation. Participants observed that with research governance, "there really isn't much in the way of career paths … as far as research assistants, staff within the ethics committees, RGOs, all of those sorts of roles" (Interview 16). The provision of standardised education was a central tenet of professionalism and how the future of NMA was perceived.

7.8.3 Summary of the NMA as a normative influence

Normative isomorphism develops from pressures brought about by professions. This occurs in two ways. Formal education introduces a legitimate cognitive reference that devalues any other approaches and the creation of professional networks that span organisations diffuse new information rapidly (DiMaggio & Powell, 1983). In the current context, Phase One findings indicated that professional standards in research governance were considered important but there was a persistent uncertainty about the nature of the relevant standards.

Phase Two built on these findings to identify the themes of "Lack of a professional recognition" and "Research governance credentials were unclear". These themes show that there was a lack of clarity regarding the roles of governance personnel or what qualifications were required to work in the area. The roles of those working in research governance are contextual, developed by the organisation to meet the workplace needs. This is in keeping with previous literature which noted that research administrators were seen as invisible because of the perceived neutrality of their roles (Dunscombe, 2008). Consequently, the NMA was perceived to provide limited normative pressures.

7.9 The future of the NMA

Interview participants were invited to focus on the future of the NMA. The majority of the interview participants mentioned the need for consistency in the single ethical review processes, but different aspects of consistency emerged in different interviews. Most participants described the need of a single research authority that would require all participating organisations to comply with the NMA (coercive influence).

Even so, participants who are involved with the NMA do not belong to one school of thought. Expectations of future directions were clearly influenced by a participant's background and how much insight they had of the current constraints of the research sector. For example, for some the concept of a single research authority was a logical development, but others recognised the legal and regulatory challenges posed in creating a body that had authority over differing jurisdictions and sectors.

However, despite the varying nature of the participants' opinions, they identified that a key driver for healthcare agencies to engage with the NMA is related to research and the NMA having value to the healthcare agencies and their stakeholders. One possible incentive for a healthcare agency to prioritise research would be to introduce performance measures that relate to funding. This suggests that the dominant driver of consistency would be coercive isomorphism. However, the interview findings also indicated that mimetic and normative pressures may be occurring at lower levels within the organisation, so that the goal of consistency could only be reached if there was recognition of all three isomorphic pressures.

In this section of the presentation of the Phase Two interview findings, the future of the NMA is divided into four parts: a sustainable future system requires consistency; the NMA as a future coercive influence; the NMA is a weak future mimetic influence; and the future normative influence is not clear. There are elements of the discussion that pertain to more than one influence. This gives support for arguments in the literature that the three mechanisms of isomorphism are inter-dependant (DiMaggio & Powell, 1983; Mizruchi, 2004) and that recognition of legitimacy may vary depending on the audience (Deephouse, 1996).

7.9.1 A sustainable future system requires consistency

Despite the concerns raised in the interviews, participants in general were optimistic about the future of the NMA if the issues they raised around consistency of the system could be addressed. Participants supported the NMA as a permanent change but identified the need for consistency throughout the system to maintain a more sustainable future system. The following observation was made by a research director regarding the need for the processes of single ethical review to assist and not impede the healthcare agency in managing its own research sector.

> In principle, streamlined review is the way to go, the only way. It should be faster overall. It should allow the individual hospitals to concentrate on their own processes while the ethics is taken care of. It should give us the confidence that the ethical review was the best. All of these things, and it should give us metrics on every step of the process. We should have an IT system that I, or those in roles similar to me, can use to print off reports that truly show real time performance (Interview 20).

There are multiple contributing factors involved in providing a consistent future system. This comment highlights the need for synchronisation between the healthcare agencies undertaking the research and the national single ethical review system. The mention of the ethics review being "taken care of" to allow individual hospitals to concentrate on their own processes, presents an overall picture of the agency operating within a wider system.

At the same time, there are indications of tension between the local needs and those of the NMA. The benefits to the agencies are contingent on the efficiency of the whole system. For example, the participant highlights the speed of the process and that agencies need to feel confident of the HREC review as well as a requirement for performance reports that meet the agencies' needs.

7.9.2 The NMA as a future coercive influence

7.9.2.1 One system, one central authority. When interview participants were asked to describe their expectations of the NMA in the future, they used terms such as coordinated, standardised and seamless to indicate a system of single ethical review through which multi-site research projects moved through various review points in a fast and synchronised manner. The most pressing requirement was that the NMA "worked the way it is meant to work" (Interview 20).

Research in the Australian healthcare system involves multiple groups, such as public and private health care, academia, business and commercial interests, which are regulated under different legislative frameworks. There are "lots and lots of big organisations around this country who are sort of dabbling in research and how to approve it" *(*Interview 16). Consequently it was argued that effective streamlining of ethical review required cooperative decision-making between these bodies to "get every single person in the same room at the one time and then say 'OK, these are the issues'" (Interview 16).

Participants identified the importance of a single research authority which had the power to compel standardised behaviours in all parties involved in streamlined review but they had different concepts of how this power would be constructed.

> There has to be the same standards … I know that we currently have multiple authorities and multiple fingers in the pie but we need a single authority (Interview 17).

> There is a need for a central research body with the authority to impose upon the individual states and territories … The NHMRC is central to research review but it does not have dominion over the states (Interview 10).

A suggested alternative to a formal authority was the creation of a set of standards or principles that would be accepted by many.

> That's doesn't mean a body like the NHMRC but maybe it's more like GCP [Good Clinical Practice]. Not law. Not strictly speaking enforceable. But if you don't have evidence that you comply, no one will do business with you. If we could get the current powers to agree to one set of standards, then I think we could work with that. Yes, I think we could work with that (Interview 17).

GCP is an international quality standard for all aspects of clinical trials. It is an accepted standard that research personnel from any participating countries are required to demonstrate knowledge of GCP to prior employment on a clinical trial.

Following this concept, the intra-jurisdictional nature of the NMA would be strengthened if compliance was driven from within the system rather than relying on MOUs, which did not apply to non-public organisations. A similar standard to the GCP guidelines could, in principle, apply to all research sectors.

7.9.2.2 Disengagement of the HRECs from healthcare agencies. Participants also drew on other models of multi-site research review particularly that of the United Kingdom (UK), to illustrate an established centralised system. Over the past two decades, the UK government decommissioned public health institutional HRECs in favour of centralised ethics and governance process.

> [In the UK system] HRECs are not associated with institutions. Applications go to the first free HREC and the identity of HREC not known to researcher. HREC deadline of 60 days is a government responsibility. Pressure can be put on government if timelines lag (Interview 15).

Participants felt that implementation of the NMA and promotion of a standardised approach to single ethical review might be assisted if the reviewing HRECs were disengaged from their healthcare organisation.

> Maybe you just have one [HREC] in every state. But the one ethics committee isn't just one group of 20 people or so who meet a certain

> time during the month. One ethics committee might be 4 or 5 subcommittees so you've got a different group of people meeting every week and you've got a huge pool of the right sort of expertise (Interview 1).

This suggests that a single committee may provide efficiencies of scale in that being able to review more projects, a larger centralised committee may offer operational efficiency, leading to lower variable cost. In other words a centralised HREC may handle a greater number of research applications more cheaply than a collection of individual HRECs.

However, for many participants, Australia was not yet ready for a totally centralised model. Currently, for example, HREC members are volunteers and they undertake HREC duties in addition to their paid employment.

> You've got to balance it because we're not paying our [HREC] members so you can't harass them or force them to be really quick. Some of them are medical people as well and they're really busy. So it's hard to ring them up and say "you have to do this now". They're volunteers (Interview 2).

Some participants were uneasy that a fully centralised ethical review system would not recognise the clinical landscape in which the study was to be performed.

> I am more concerned when people say we'll have a central committee that going to review everything because you lose the expertise of a link of between ethics and governance (Interview 11).

As participants continued to reflect on the impact of the NMA on their own practices, indications emerged of tensions between their need to balance organisational needs against the directives of a single centralised authority. Participants stated that public healthcare organisations concentrated on their own core responsibilities of standardised clinical care and financial stewardship which limited their support for the national research review model.

7.9.2.3 The need to engage the whole agency. While the NMA was seen as a permanent change by those directly involved with research review processes, participants reflected that the complexity of their large organisations tended to retain the existing organisational focus.

> Each health service has such inertia. To change the requirements of the health service based on meeting governance for clinical trials, isn't going to happen so the governance needs to fit with what's required by the health service (Interview 11).

Research is only one of many activities undertaken in healthcare. Healthcare agencies are very complex and involve many stakeholders.

> You've also got lot of different committees around the place: hospital research managers, the RGOs, other state bodies and other committees that I don't even know about. They are all pulling different ways on what should happen. So you've got all these different thoughts, five or six pathways. Basically all these groups need to be pulled in together. There has to be a paper saying "this is the way we handle it" (Interview 5).

Hence, exploring the future of the NMA highlighted the necessity of public health organisation as decision-makers in the NMA processes, so they are able to plan the implementation of government strategies in ways that recognise the needs of the organisation.

> It would be much better to have the Department of Health as a partner in change rather than the parent imposing it on us (Interview 9).

The size and complexity of healthcare agencies meant that cultural change did not happen quickly. Definitions of what was important in managing research and the scope of the organisation's research governance obligations varied between agencies and between agencies and the DHHS.

7.9.2.4 Metrics that reflected the scope of site governance. As participants continued to reflect on the future of streamlined ethical review, they noted that the organisational view of research governance is more frequently considered to include the total life cycle of a research project, not just the activities involved in site authorisation.

For example, it was noted that "historically timelines related to the ethics/governance processes but in actuality covers a far broader span" (Interview 3). In order to address the principles of the NMA, particularly timeliness, there was recognition that

> … areas outside the ethics approval/RGO authorisations are important to act on e.g. measure discrete times between actions as well as overall performance, establish a reasonable timeframe, audit and discuss the findings with the investigators (Interview 3).

This approach was notably different from the principles underlying the NMA and the dedicated IT system that emphasised only the processes around the research application and approval. To appreciate the scope of institutional responsibilities around the governance of research, it was important to

> …map out every step of the way. What happens at every step and why. What's good, what's not good and where it is at … how many feasibility studies turn into site selection and of the ones that don't, why not, and for the ones that do, why (Interview 1).

Subsequently, the responsibilities were found to range from when the study was first proposed through to the long term archiving of the files from completed studies. The processes through which a study achieved ethical approval or site authorisation were only one section of the whole span of performance and measurement.

7.9.3 The NMA is a weak future mimetic influence

Mimetic coercion involves decision-makers deliberately making an effort to obtain information about other organizations in order to imitate them (Villadsen et al., 2010). When participants reflected on the future of single ethical review, they highlighted the

need for consistency in the system, indicating that the main influence of the NMA on public health organisations remains with the government, or possibly the theoretical single authority which had the power to compel standardised behaviours in all parties involved in streamlined review.

The difficulty with agencies adopting practices outside the *Standard Principles for Operation of National Mutual Acceptance of single scientific and ethical review provided by the DHHS* (Victorian Department of Health and Human Services, 2016a) is that it may impact others who rely on that agency.

> Well again, I don't want people to be doing random things. I like it to be consistent … So I don't want people saying, for example, – "oh I'm just going to do this PICF. You've just got to wear the consequences" (Interview 19).

As noted above, participants emphasised the need for consistency and adherence to the NMA guidelines, which suggested that the role for mimetic isomorphism within a national system is limited.

7.9.4 Future normative influence is not clear

When participants reflected on the future of the NMA, they identified a significant need for professional input from those working within the sector. This involved a strong and consistent knowledge base, opportunities to network and opportunities to voice suggestions and complaints regarding the NMA.

7.9.4.1 Strengthened knowledge base. Effective decision-making and administrative operations in research governance require a comprehensive knowledge base of the research landscape and any relevant development trends. Knowledge is not only needed for implementation but also for evaluating the impacts of policies, decisions and measures. Participants identified education, career opportunities, credentialing and mentoring as mechanisms to promote a body of professional knowledge within research governance. They also identified a need to understand the appropriate processes involved in the NMA.

> A lot of people don't seem to have heard of the SOPS [Standard Operating Procedures published by the DHHS] … My feeling is that it would work if people followed the way it should be done. We should all be clear about how it should be done in the first place and then we wouldn't spend so much time chasing our tails (Interview 20).

There were also recommendations for senior levels within the organisations to be educated on the role of research and the requirements of the NMA.

7.9.4.2 The need for professional networks. Participants spoke highly of collaborations such as Hospital Research Directors Forum (HRDF) and the Victorian Research Governance Network (VRGN) that are convened to enable information sharing and collaborative action, especially in research governance. The implication is that professional networks contribute to the future direction of research administration through exchange of viewpoints.

> So how to get a voice? Through the network and also through participating in workshops and forums and asking questions like we just did. We get to find out if we are all having the same issues or am I the only one. I think a forum would be good (Interview 9).

7.9.4.3 A voice for all. None of the networks or forums, however, was perceived as able to provide a consistent channel for concerns or suggestions. This was identified as a lack in the current system and a critical component of developing a future system. This was a source of great frustration to both the regulator and researcher groups.

> I would observe that across the country there are a lot of people sort of biting their tongues with feedback. There's no clear place to go. (Interview13).

> [Interviewee reflecting on whether there was a complaints mechanism] Actually no. Not really. … I don't know who to talk to, I actually don't know. I don't know who to complain to (Interview 7).

> I've taken it to the CEO who has mentioned this to other people. I've taken it to the research director's forum and … told the Department directly (Interview 11).

Other participants raised concerns about their lack of contribution to the development of the system. This was particularly pressing in times of change.

> So this new electronic system, which we were not consulted about, has now led to calls from researchers on what to do and we say "we have no idea. That's not our job" (Interview 6).

Many participants felt that "there's not a clear answer to who actually has the power. There's certainly concern about different groups with different influences" (Interview 13).

7.10 Summary

Phase Two of the research involved individual semi-structured interviews, the purpose of which was to develop a deeper and broader understanding of the ways public healthcare agencies engaged with the National Mutual Acceptance (NMA), and how the NMA was likely to impact in the future. The interview questions were influenced by the findings of the Phase One survey. In particular, the persistent presence of uncertainty in the Phase One responses encouraged the researcher to be sensitive to the possibility that different participants might view the impact of the NMA quite differently.

In order to understand the issues, Phase Two involved a purposive judgement sample of "research leaders", who were personnel actively involved in developing awareness of multi-site research and streamlined review. Of the 21 interviews, 15 participant were employed in a regulatory capacity, 4 worked as researchers or clinical trial coordinators and 2 described themselves as researchers involved in regulation. The majority (15) were either middle or senior management and 6 stated they were non-managerial. Within this group, the terms Applicant and Regulator were less prescriptive as most had some experience of the other role, such as serving on an HREC or another committee that involved multiple stakeholders.

There was a general support, in principle, of the NMA approach to the review of multi-site clinical trials in the public healthcare sector. At the same time, concerns were expressed at the inconsistencies within the system, particularly the development of agency practices outside the standard guidelines, and difficulties with the dedicated IT system. Thus, while participants accepted introduction of the NMA, they also portrayed a system that was burdensome and did not fit well with their local practices.

Coercive isomorphism was perceived as the dominant pressure from the NMA. Government has the authority to introduce a change of practice into the public healthcare sector. However, inconsistencies within the NMA limited the realisation of its goals and its coercive influence. Thematic analysis found that the lack of consistent leadership in single ethical review to be of concern.

Limitations in the coercive pressure of the NMA and inconsistency of the system were perceived to impact the influence of mimetic and normative pressures. Although Institutional Isomorphism theory posits that uncertainty increases the likelihood of organisations copying the behaviours of others, the findings from this study suggested that healthcare agencies were not seeking greater legitimacy through the NMA. Their focus remained on their own activities. There was indication that mimetic behaviour was occurring but at middle rather than senior management levels. Perception of normative pressures was also limited as participants described research governance roles in a local rather than broader context.

These findings continued into the participants' visions of the future. In general, participants identified the need for coercive pressures to enable consistency of the NMA system. At the same time, they recognised that health research involves many partners, including academic, business and other entities from the private and not-for-profit sectors, that were not bound by the obligations to state and territory governments. Mimetic and normative influences did not feature highly in how the participants viewed future strategy involving the NMA. The discussion of these findings in relation to the research questions are presented in the following chapter, Chapter Eight.

CHAPTER EIGHT: ANALYISIS AND DISCUSSION OF RESULTS

8.1 Introduction

The results of the statistical and interpretive analyses as well as content analysis of semi-structured interviews were reported in the previous chapters. The aim of Chapter Eight is to provide the interpretation of the results in relation to the research questions.

This chapter is structured as follows: Section 8.2 presents the research questions on which the discussion is based, while Section 8.3 provides a short summary of the theoretical basis to the study. Section 8.4 and Section 8.5 position the findings from the survey in relation to current literature. An overview of the impact of respondent demographics is provided in Section 8.6, noting the importance of work experience to these results. The acceptance of the hypotheses is presented in Section 8.7, noting that the division of Applicant and Regulator was not as dominant as expected. Sections 8.8 and 8.9 explored findings of the current and future expectations of the NMA. Section 8.10 examined the effectiveness of the conceptual model in predicting behaviours within a complex environment and the results of triangulation were presented in Section 11. Section 8.12 concluded the chapter.

8.2 Research question

The study was undertaken to address the question:

> What are the coercive, mimetic and normative pressures that influence public healthcare agencies in Victoria to comply with the National Mutual Acceptance?

8.3 Theoretical basis

Institutional Isomorphism provided the theoretical basis to this study of how the National Mutual Acceptance (NMA) impacted on the research governance practices of Victorian healthcare agencies participating in multi-site clinical trials. The basic tenet of the NMA is the consistency between entities so that processes are predictable.

Institutional theorists assert that the development of formal structures in organisations are strongly influenced by the institutional environment, and that organisations facing the same environment constraints tend to develop similarities. Thus, institutional theory provided the basis to the conceptual model and the lens through which the research question was examined.

8.4 Phase One: the current influence of the NMA

8.4.1 The importance of research

The concept of organisations striving to appear legitimate to increase the possibility of their survival is a foundation of Institutional Isomorphism (DiMaggio & Powell, 1983). Organisations facing the same environmental constraints are inclined to develop similar behaviours to satisfy stakeholder requirements, although the literature also notes that different stakeholders may view legitimacy differently (Deephouse, 1996). The implication in this theory is that the issue forcing the behavioural modification is important enough to impact survival of the organisation. This is particularly relevant to the complexity of public healthcare agencies that provide numerous services and multiple stakeholders.

Public health services receive government funding based on specific deliverables of clinical services within set timeframes. The expected activity, required to receive the funding and details of expected administrative and clinical conduct, is set out by contracts at an organisational level, primarily Statements of priorities (SoPs) and service agreements (Victorian Department of Health, 2013c). As yet, no expected research activity has been included in these contracts, and, at the same time, Victorian agencies are expected to devise their own clinical risk management and governance programs.

The Phase One survey invited respondent to rank their expectation and experiences of hospital research. Nearly all respondents indicated strong expectation that research should be regarded as important and that this should be reflected in written site policies and procedures. Regulators indicated greater support for the reporting of research performance measures and significant issues (such as ethical breaches) to the Board. In relation to whether research is regarded as a core activity in real life, over three quarters of respondents did not agree.

These responses suggest that research is ambiguously positioned in healthcare agencies. Although clinical research differs from standard care and the growth of multi-site research emphases the need for inter-organisational cooperation, in most health service it has not yet obtained the critical mass required to establish a distinct sector. Senior personnel were perceived to have limited knowledge of the specific practices of research governance and thus research was not considered an integral component of hospital activity. The exception was promotion of research activity such as research week where individual effort was highlighted.

In respect to the theory of Institutional Isomorphism, this suggest the likelihood of research providing a weak legitimacy target and, furthermore, that the susceptibility of healthcare agencies to coercive, mimetic and normative pressures is uncertain because research is not impacting their survival.

8.4.2 Coercive influence

Public services are generally viewed as vulnerable to coercive pressure, because of their funding dependency on the government (DiMaggio & Powell, 1983). The NMA meets the conditions in which coercive pressures should apply. It applies to the clearly defined organisational field of public health agencies involved with multi-site research, the change was strategic and top–down with clear targets for organisational success. While the NMA influence to manage organisational behaviours drew most obviously upon coercive pressures it also presented opportunities for normative and mimetic forces to develop.

The majority of survey respondents supported the importance of the NMA to hospital research regulation, but Regulator responses showed slightly less support than Applicants and showed greater uncertainty. Regulators were slightly less supportive than Applicants in relation to expectation of generic feature of the NMA: fast authorisation, advice consistency and research governance compliance. In response to more specific operational items, such as whether responsibility for compliance to the NMA should rest with management, support across both groups diminished while uncertainty and disagreement increased. The lowest level of support was recorded for

the final item of the set where respondents were asked to rank their experiences of the impact of the NMA. Half of Regulators indicated support that the NMA did influence governance practices but nearly three quarters of Applicants indicated uncertainty or disagreement.

This finding was in keeping with observations made UK literature exploring the impact of moving from local practice to centralisation. Howarth et al.(2008) argued that centralisation of processes assisted in building a research culture because organisations were able to develop their capability and capacity building, rather than investing in infrastructure. However, there was potential for centralisation to result in loss of local autonomy.

Other theorists have further addressed the complexities of managing organisational legitimacy within an institutional environment where acting upon certain norms, values and rules to gain legitimacy may conflict with local aims. Ashworth et al. (2007) made two observation on the impact of isomorphic pressures. They identified two definitions of conformity (compliance and convergence). The term compliance suggests that, over time, organisations are reflecting the isomorphic pressures, for example in keeping with government strategy. The term convergence refers to the extent to which organisations grow to resemble each other. This can happen with or without compliance. They also found that different areas of an organisation might be more vulnerable to isomorphic pressures than others. Compliance is strongest in organisational culture and strategy but weakest in structure.

Decoupling is a process of deliberately creating and maintaining gaps between formal policies and actual organisational practices. Scholars have argued that decoupling enables organisations to gain legitimacy with their environment while simultaneously maintaining internal flexibility to address practical considerations (Boxenbaum & Jonsson, 2008; Meyer & Rowan, 1977).

Decoupling of organisations from the expected NMA processes was problematic for both Applicants making a submission because they had to check the specific requirements for that organisation as well as for those “downstream” of changes in

practice. While it may have met the immediate needs of the organisation, it compromised the integrity of the NMA as a system and created uncertainty.

8.4.3 Mimetic influence

Uncertainty, according to institutional theorists (DiMaggio & Powell, 1983), provides the impetus for mimetic pressures to develop as organisations look to their peers for the best practices. Unlike the coercive influence provided by the NMA, mimetic influence develops as agencies deliberately seek to understand and then mimic the actions of successful counterparts. The findings from this study did not suggest that mimetic practices around the NMA were occurring at organisational level.

Greatest support was provided for the more generic item of whether the NMA should set up target time for approval, but Regulators were more supportive of operational opportunities such as networking and comparison between research offices. They were also more likely to agree that the NMA does set standard approval time. However, Regulator responses also showed a high standard deviation, signifying that the data points were spread out over a wider range of values than the Applicant group and suggesting less unity in the Regulator group.

8.4.4 Normative influence

Normative isomorphism refers to the pressure exerted through cross-institutional social mechanisms that collectively define the appropriate ways in which members of that group should act. Thus, isomorphism occurring on the basis of normative pressures is associated with professionalism (DiMaggio & Powell, 1983). Professional standards are imposed through education and endorsement through professional associations, which "have a strong motif of keeping the standards (e.g. accounting associations)" (Janićijević, 2014, p.252).

Within the current study, data collection for the NMA as a normative influence focussed on the expectation of professionalism within the research governance sector of public healthcare agencies (see Appendix H). Although the NMA centres on the timeliness of the HREC approval, there is an expectation of comparative promptness in research governance practices involved in site assessment of the project. Thus in this context,

professional standards in research governance, while not a direct measure of the NMA, were allocated proxy status and considered strongly related to the NMA. Professional standards in research governance were used as a measure of the NMA impact as a normative influence.

The study found that more Regulators supported the need for professional standards than Applicants and that Applicants also indicated greater uncertainty. Applicants showed their lowest levels of agreement when asked if research governance units do have professional standards in reality.

8.4.5 Do Applicants and Regulators view the NMA differently?

The process of research review embodies two separate activities. One is the preparation and submission of an application for consideration of reviewing bodies. The other activity involves the reception of the research application, ensuing that it meets ethical, regulatory and organisational requirements. This suggests a logical division of culture and practices between Applicants and Regulators, which is supported in literature describing how bureaucratic delays impede research (Salman et al., 2007; Webster & Temple-Smith, 2013; White et al., 2016). Clinical trial literature has also described lack of timeliness and transparency as a disincentive to commercial partners (Clinical Trials Action Group, 2011; Health Outcomes International, 2015; Manville et al., 2013; NSW Ministry of Health, 2013).

The Independent Samples t-test (or Student t -test) was used to determine any statistical significance in the differences between Applicant and Regulator responses. The majority of differences in the survey responses were not shown as significant, although significance was shown for greater Applicant support of fast research authorisation and greater Regulator support for regular opportunity to network and the expectation of professional standards for research governance personnel. Together, findings from these items suggest that the Applicants' perspectives is dominated by the outcome of the research review process and the Regulators are more concerned with the practices of research governance. However the high levels of uncertainty in the findings also suggest that the respondent's role is not the only influence on how they view the impact of a national system on hospital practices.

8.5 Factor analysis and regression

Further exploration was undertaken using factor analysis and regression. Factor analysis was used as an exploratory measure of the robustness of the survey, including the reliability of the constructs and the validity of the variables in each construct. All Likert-scaled variables were subjected to factor analysis. The principal component method was used to extract six factors, as shown in Table 8.1.

Table 8.1: Composition and definition of factors

Factor	Definition	Survey constructs
Comparison	Comparison with peers;	Mimetic Influence
Authority	Authority of the NMA;	Importance of research Coercion influence Mimetic influence
Standards	Endorsement of professional research governance standards;	Normative Influence
Reporting	Reporting to the Board;	Importance of research
Standard Importance (Stan. Import)	Importance of the adoption of professional standards in research governance and	Normative influence
NMA Importance (NMA Import)	Importance of NMA to hospital research regulation.	Coercion influence

While the factors indicate the constructs of Institutional Isomorphism on which the survey was based, they represent latent factors or underlying beliefs and perspectives. Each factor can involve more than one construct of the survey and constructs can be represented in more than one factor. This crossover between the constructs of Institutional theory is supported in literature (Mizruchi & Fein 1999).

Regression analysis was used for estimating the relationships among variables, using one factor as a dependent variable and the remainder as independent variables (or 'predictors'). The analysis incorporated demographics as independent variables so assess whether they provided a moderating influence. As indicated in Table 8.1, no variable stood alone but was associated with others.

The importance of research represented in the association between Authority and Reporting, suggests that regard for the importance of research in hospitals involved elements of all isomorphic influences. Findings also showed that respondents who anticipated that hospitals should regard research as a core activity were also more likely to be less experienced or at a lower organisational level.

Support for the NMA providing coercive influence was overtly reflected in the factor NMA Importance but also a component of the factor Authority. Analysis of these factors suggest that support for the NMA providing a coercive influence is associated with recognition of the importance of NMA to hospital research regulation and to mimetic processes. Less experienced respondents indicated stronger support for the NMA providing a coercive influence but those from older age brackets and Regulators indicated weaker support.

Mimetic influence was reflected in the factors Comparison and Authority. Analysis suggests associations with factors involving the importance of research and the NMA providing normative influence. Females were more likely to support the NMA as a mimetic influence. The impact of role and years of experience was not clear as analysis showed different relationships with the different factors.

How the NMA operated as a normative influence was indicated in the factors Standards or endorsement of professional research governance standards and Standard Importance or the importance of the adoption of professional standards in research governance. Respondents were more likely to endorse standards if they felt they were important.

8.6 Impact of demographics

A limited range of respondent demographics were collected to enable the basic structure and composition of the defined population to be established. They were age, education, gender, role (Applicant or Regulator), level (management or non-management) and years (length of experience). Analysis of Phase One data indicated that all the demographics, with the exception of education, were significant in this data collection. Survey respondents aged 50 or over were less supportive of the authority of the NMA; female respondents more likely to endorse professional research governance standards,

Regulators were less likely to agree with the authority of the NMA but more likely to agree that research governance standards are required; more managers than non-managers agreed with reporting to the Board and those with 6 or more years' experience in their roles were more likely to support the authority of the NMA and the comparison of governance practices but less likely to endorse professional research governance standards.

Demographics have emerged in this study with greater weight than, for example, in the literature of the UK experience which involved a statutory framework introduced by a central government. In the Australian experience, there is no statutory framework so that the operationalisation of the NMA falls largely to the participating organisations. Years of experience was particularly significant. The literature suggests that late-career employees, in comparison to the early and mid-career employees, were perceived to have strong work ethics, loyalty to their employer and low turnover rates. However, they were also perceived to be the most resistant to change, reluctant to try new technologies and difficult to train (Centre of ageing and work, 2010). This is suggestive of the findings from this study.

8.7 Acceptance of the hypotheses

The research findings from Phase One supported the predictions contained in H1, that adoption of the NMA was positively related to organisational recognition of research activity (legitimacy), and H2, that the operation of the NMA was positively related to isomorphic pressures. However, as discussed, these associations were less robust than literature suggested. In particular, participant demographics impacted the association. The prediction of H3, that perception of adoption and operation of the NMA was positively related to respondent role, such that the effect will be stronger for Regulators than other demographics, was found to be only partially supported. While role was associated with the factors authority of the NMA and endorsement of professional research governance standards, other demographics were also found to be significant in influencing perceptions of the NMA.

8.8 Phase Two: exploring current and future perceptions

Semi-structured interviews were conducted in Phase two of the study to explore the current perceptions of any Isomorphic Impact of the NMA and explore any predictions of the future.

8.8.1 Legitimacy and leadership

The interview findings revealed limitations in how the NMA was regarded by healthcare agencies; a finding which mirrored Phase One survey findings that research was also not highly regarded. These are meaningful findings because they imply that isomorphic influences, which are aimed at achieving legitimacy, will also be restricted.

Effective leadership at all levels was identified as a critical element of the NMA. The government had the authority to mandate change of practice in public healthcare agencies, but adaption of the NMA into a healthcare agency was affected by the leadership from within the healthcare agencies. Attitude of Boards and senior management controlled the agency environment which impacted on how operational practices supported NMA goals.

Literature has identified leadership as a critical function of management to maximise efficiency and to achieve organisational goals, especially in areas, such as health, where changes are ongoing (Burnett et al., 2016; MacLean & Behnam, 2010). A study of hospital management found response to challenges was dependent upon three criteria: the coherence of demands; managerial competence to align demands with an overall quality improvement strategy, and managerial stability (Burnett et al., 2016). The study findings suggest these criteria are not well met for the NMA. The demand for a national system is countered by pressure for organisations to retain a local focus consistent with existing quality improvement strategies. The complexity of research governance especially in regard to clinical trials was not considered at a senior management level. In effect, the NMA requirements were met by the research office leading to a decoupling between the more overt electronic submissions of research and the actual implementation of changed service delivery.

The interviews revealed that concern about inconsistencies in the way the NMA was managed and that the NMA requirements did not synchronise with those of the healthcare agencies. This ambiguity of purpose placed those involved with the NMA in an uncertain position, and consequently the legitimacy of the NMA itself was indeterminate as an organisational goal.

8.8.2 Coercive pressures and decoupling

Both Phase One and Phase Two findings supported the expectation that the NMA would provide a coercive influence on research governance practices, but their experience was that organisations retained many of their own practices. This concept of decoupling from the institutional environment is a key concept in institutional literature.

Institutional theorists maintain that organisational behaviour develops from values and beliefs that originate in the institutional context (Meyer & Rowan, 1977). The survival of an organisation is dependent on its ability to accommodate institutional expectations, even when these expectations have little or nothing to do with its technical performance (Scott 1981; Scott & Meyer, 1982). Thus, organisational behaviours involve responses to market pressures and also the institutional context. Organisations need a societal mandate, or legitimacy, to operate and this is gained by conforming to societal expectations which leads to institutional isomorphism. However, when institutional and task environments are in conflict, or when there are conflicting institutional pressures, organisations decouple their formal structure from their production activities. Decoupling is the creation and maintenance of gaps between formal policies and actual organisational practices (Meyer & Rowan, 1977) and enables organisations to seek the legitimacy that adaptation to institutional provides while they engage in technical 'business as usual'. Decoupling is more common when there is weaker competition between organisations or when efficiency is harder to measure, such as in public service organisations (Meyer & Rowan, 1977). However, decoupling compliance functions can be detrimental (MacLean & Behnam, 2010).

8.8.2.1 Decoupling

Most interviewees recognised that decoupling was occurring. They described the complexities of the interaction between the objectives of the NMA goals and

infrastructure surrounding healthcare agencies. Within the health sector, there are many formal structures and socio-cultural components that interact at federal, state and organisational levels. A national arrangement requires the different subsystems to forge alliances so that they are able to come together in a new infrastructure. Interview data highlighted the complexity of these interactions and that the evolution of isomorphic influences in this sector is not straightforward.

Government strategy

Similar to the survey responses from Phase One, the NMA was supported in principle, with the motivation for the program stemming from government. Government and public health organisations are situated within the same socio-political sector but they differ in how they strategically situate their operations to make them viable. Changing environmental constraints provoke each entity to a continuous search for solutions but theses searches are informed by the life experiences and demands relevant to that entity. The respective strategy needs to manage issues as consensus between stakeholders, legitimacy, scarcity of resources and sustainability, to positon that entity favourably. Although, the study findings found support for the single ethical review in principle, the findings also highlighted disparity in the infrastructure around the NMA.

Disparities between government aims and what the healthcare agencies involved in research saw as important was demonstrated through discussion of performance reports of time to site authorisation produced by the Department and which had engendered disquiet in some senior Regulators. The reports used the start of the ethics review as a baseline to the time to site authorisation. To the organisational personnel, this measure was not appropriate if they were late invitees to the study or had not yet received the study materials. So the sites were concerned with their individual times but the overall review time was most relevant to government. Thus the government focus was perceived as on the overall endpoint (timeliness) whereas the interviewees did not.

This finding is consistent with previous literature that suggested addressing specific local governance issues may conflict with the goals of a consistent national model (Franck et al., 2004) and the consequent likelihood of organisations decoupling from inappropriate directives (Boxenbaum & Jonsson, 2008; Burnett et al., 2016; Meyer & Rowan, 1977).

Differences at jurisdictional level

In Australia, legal and regulatory requirements of researchers may differ between jurisdictions (National Health and Medical Research Council, 2014c). This contrasts with other countries, such the UK, where the Health Research Authority and the health departments in England, Northern Ireland, Scotland and Wales have developed a policy framework for medical and social research to replace the separate frameworks in each country (National Health Service, 2014). In Australia, a reviewing HREC must be mindful of when their decision is to apply in jurisdictions with different compliance requirements. Ethics decisions, while not law themselves, are embodied in in community values, including law and other standards which have ramifications for non-compliance.

Organisational field level

The study found multiple places where the infrastructure needed to sustain the NMA was compromised at the organisational field level. Similar to the Phase One findings, the main impact of the NMA was observed to fall on the processes around submission of a research project for review.

At the intersection between the researcher and the research office, both technical and socio-cultural differences between participating sites were evident. The study found that technical issues, such as organisational technology as well the speed and design of the dedicated IT system played a part in how research office personnel were likely to comply with the operating procedures. Socio-cultural arrangements that involve beliefs, customs, practices and behaviour within an agency population impacted on how practice changes were viewed.

The practical implications of these issues led to variations in ethics and site governance submission processes. For example, retention of a paper filing system by a healthcare agency meant that the research office developed locally specific practices in addition to the application made through the dedicated IT system. Applicants expressed concern that variations in what was required to make a submission for ethics review or how quickly errors in the ethics notification were rectified drove them to limit the HRECs they applied to. This is contrary to the assumptions of the national system, which is that applicants may apply at any accredited HREC.

Lack of adherence to the NMA operating procedures led to lack of trust in the ethics submission process from accepting sites. The result of locally specific practices was that, although there was formal recognition of the NMA, there was limited engagement with the principles of streamlined review by the healthcare agencies. Agencies retained their own identity in their decision-making, which was seen as problematic by downstream or accepting agencies. They indicated that they were disadvantaged because of provision of their study materials was often delayed and inconsistent.

8.8.2.2 The impact of decoupling

According to Meyer and Rowan (1977), organisations are not simply the product of increasing technical sophistication but are the result of the increasing rationalisation of cultural rules. Each organisation is a component of a wider social system, serves as the source of legitimacy that makes the implementation of the organisation's goals possible. Within Victoria, each healthcare service participating in the NMA is expected to comply with the standard operating procedures (Department of Health & Human Services, 2015). The dangers of decoupling organisational compliance to the expected practices is repercussion on those "downstream" from that action. Decoupling has created a façade of legitimacy that has enabled institutionalisation singularity and precipitated a loss of external legitimacy.

"Downstream" or accepting sites included personnel engaged in regulator and applicant activities. Interviewees raised concerns that HREC decisions which did not conform to their organisation's expectation may expose the organisation to risk. This referred, for example, to interstate reviews whether the specific requirements of Victorian legislation had not been considered in the HREC review. Victorian organisations that are a signatory to a Memorandum of Understanding (MOU) with the Department of Health and Human Services must agree to accept the ethical and scientific review of a reviewing HREC and not undertake any further review by the organisation's HREC. Participating sites undergo a process of site specific assessment (SSA) that will be conducted by the participating site as part of an institution's research governance responsibilities (Department of Health & Human Services, 2015). This raises issues around how the responsibility would be shared out amongst stakeholders. Currently,

there is no specific scheme or arrangement regarding insurance or indemnity for clinical trials that are ethically reviewed and conducted under the NMA (Rallis Legal, 2014).

Furthermore, decoupling also raises questions of the role of the regulatory personnel in the accepting sites, and whether, for example, the responsibilities for determining a discrepancy would be the same at a smaller site, doing few multi-site projects, as for a site doing a great many. Lack of clear role definitions for research administrators has been identified in previous literature (Dunscombe, 2008; Kasule et al., 2016). Lack of consistent trust in the ethical decision meant that research governance personnel at accepting sites felt the need to reconcile the ethics notification of approved items and processes with their expectations.

8.8.2.3 The business of research

As randomised controlled trials have become the 'gold standard' for medical research, the operational and financial aspects of multi-site trials have emerged. Multi-site research requires all participating sites to be operating at the same milestones of the research protocol, a document that lists the required activities for the project in detail. This ensures consistency of the data collected at all sites. It also ensures the overall timeliness of the study, meaning that the window of recruitment, where participants are allowed to be recruited to the trial, is often limited. The potential for decoupling from the expected administrative processes sometimes had a profound impact on governance authorisation of accepting sites.

Commercial trails remunerate each site for recruiting a target number of participants. Sites that do not meet their recruitment target risk comprising the contractual obligations to the commercial body, which might influence the likelihood of participating in research in the future. Insufficient recruitment also results in budget imbalance, meaning that the anticipated study funds required to perform the study at that site are not met, and may terminate the study at that site. Early termination of a study may lead to ethical implications if study participants have been exposed to risk without completing the program. Insufficient recruitment also results in missed opportunities for patients who can benefit from clinical trials, wastes time, funds, and other resources.

While the NMA approach to single ethical review of clinical trials within the publicly funded health sectors of each State and Territory is a government initiative, participants identified many inconsistencies in the way that multi-site research applications were managed. This decoupling limited user trust of the system and diminished the coercive impact of the NMA.

8.8.3 Mimetic and normative pressures

The study found that weak coercive pressure impacted negatively on the development of mimetic and isomorphic influences, supporting literature that argues that isomorphic influences are interconnected (DiMaggio & Powell, 1983; Mizruchi & Fein 1999). The findings from this study did not support previous findings of the power of mimetic pressures on organisational behaviours (Barreto & Baden-Fuller, 2006; Frumkin & Galaskiewicz, 2004; Haveman, 1993; Tingling & Parent, 2002; Villadsen et al., 2010). In contrast to coercive isomorphism, mimetic isomorphism refers to the tendency of an organisation to deliberately imitate the structure of more successful peer in the belief that the structure of the latter organisation is advantageous. Mimetic pressures are thought to increase in times of uncertainty.

Although findings from the Phase One survey suggested that interview participants would support mimetic influences, this did not eventuate. Some interviews indicated that, because of organisational differences, a practice that worked well in one agency may not apply at another. They also indicated that mimicry between organisations would conflict with the goals of a consistent national model. Although this was not stated overtly, there was inference that mimetic influence might impact as a divisive rather than a cohesive pressure. For example, rather than copying a practice than aimed at compliance with the NMA, there was indication that decision-makers could mimic non-compliance. Literature has noted that not all mimetic pressures exert a positive effect on an organisation's productivity (Barreto & Baden-Fuller, 2006; Campion & Gadd, 2009; Frumkin & Galaskiewicz, 2004; Haveman, 1993; Tingling & Parent, 2002; Villadsen et al., 2010).

Interview results suggest that it is unlikely that the NMA could provide a strong motivation for normative influences to develop, unless the ambiguity of the NMA

processes could be resolved. Participants highlighted a lack of standardisation of roles and responsibilities so that research governance personnel from different agencies may hold the same title but different tasks. When they spoke of professional recognition and guidance on the qualifications required for a research governance role, participants discussed the operations of specific workplaces. They noted that any training and education in research governance was generally inclined towards specific aspects of a governance role. This indicated a predominant focus on local interests rather than the centralised system. Participants tended to agree with a localised approach rather than a higher degree or equivalent in research governance. In particular, they favoured workplace experience and mentoring as mechanism for creating governance expertise.

The findings from Phase Two denote a system of contradictions. While the NMA approach to single ethical review of clinical trials within the publicly funded health sector is a government initiative, this study identified many inconsistencies in the way that multi-site research applications were managed. There was evidence that, as suggested Meyer and Rowan (1977), agencies were only abiding superficially without necessarily implementing the related practices.This fostered an environment of uncertainty and diminished confidence in the system. Thus, while coercive pressure from the NMA provided the strongest isomorphic influence on healthcare agencies to behave in similar ways, uncertainty diminished the ability of the NMA to provide legitimacy goals. In turn, goal ambiguity and focus on individual healthcare agency needs reduced the developmental capacity of mimetic and normative pressures.

8.9 Future influence of the NMA

The foremost factor in how the future of the NMA was perceived was the requirement for consistency. Generally participants envisaged that consistency could only be achieved through coercive influence.

There was general agreement amongst participants that a single system with one central authority was required to ensure compliance with the NMA goals. It was not clear how a central authority could be established. Consistency would be difficult to establish through current regulatory frameworks as each sector has different legal obligations.

Other suggestions included national research quality standards and that research review should be added to the performance indicators of healthcare agencies' CEOs.

There was a need to minimise variation between healthcare agencies to standardise user experiences of the research review. This meant synchronisation between the standards, priorities, and performance goals of the NMA and the participating healthcare agencies. The processes for ethical approval and site authorisation comprise one aspect of research considerations but healthcare agencies also need to consider a continuum of issues, which range from site feasibility to ongoing research oversight.

When Australia introduced single ethical review in 2007, the concept of research metrics[12] was virtually unknown in public healthcare agencies and thus there was little demand from agencies for the dedicated IT system to produce reliable feedback. Now, however, participants indicated the importance of metrics to assist them in managing their own research capacities.

Visions for the future of the NMA were multifaceted and complex. Rationally, interviewees recognised that the concept of a single interconnected system is a logical response to the bureaucratic wastage that occurs when each participating site of a multi-site research project undertakes its own ethical review. It is also a logical mechanism to provide a significant component of research reforms intended to produce fast, predictable approvals of multi-site research which would then increase Australia's chances of hosting international, commercial clinical trials. In reality, interviewees prioritised their own needs and the requirements and capacities of their own individual healthcare agencies. Neither mimetic nor normative influence were overtly identified as a strategy for the future of the NMA. However, a requirement for user involvement or a "voice" was identified in several interviews where participants were concerned that involvement with the NMA impeded their workflow.

[12] Research metrics in this context differs from university measures such as citation counts, journal impact factors and researcher specific metrics that provide means of measuring research impact. Relevant metrics associated with the NMA relate to numbers and types of research as well as the timeliness of review processes

8.10 Application of the conceptual model

The conceptual model, presented in Chapter Four(Figure 4.2) was created to partner institutional isomorphic theory and four measures that can be used to quantify elements of the research environment, through which healthcare agency research strategy could be linked to organisational legitimacy. This model assumed direct relationships between the isomorphic mechanisms, coercive, mimetic and normative pressures, and stakeholder endorsement.

The study found partial support for these propositions and for the consequent hypotheses, which were discussed in Chapter Six. These limitations relate to the complexity of the intersection of the NMA goals with research governance strategy of the participating healthcare services, which has been demonstrated through the analysis and discussion of the findings. Thus whereas the conceptual model indicates a single association between the Isomorphic Mechanisms and corresponding NMA Legitimacy driver, these study findings showed that development of normative and mimetic pressures were associated with the strength of the coercive pressures and that competing pressures from the surrounding environment also influenced how isomorphism developed.

Institutional theory is normally associated with explaining how organisations, over time, develop similar behaviours to their peers (DiMaggio & Powell, 1983; Scott 1981). It has also been used to explain change in organisations (Palthe, 2014) and used as a comparator to, for example, strategic choice in organisational decision making (Child, 1972; Johnston, 2013).

It has long been recognised that public policy is a complex and multifaceted process (Edwards et al., 2012) involving the interplay of many parties. By emphasising how the play of coercive, mimetic and normative elements in the institutional context are confounded by conflicting environmental factors, this model may inspire scholars to further study studies examining the effects of these institutional dynamics.

8.11 Triangulation of the data

In the current study, triangulation was used to corroborate the findings from the separate phases. As described in Chapter Five of this thesis, it was based on three criteria outlined by Venkatesh et al. (2013):design validity, measurement or analytical validity and inferential validity through which quantitative and qualitative data collections can be compared.

Findings from each phase indicated a general expectation that the NMA would provide a coercive force, but this was not supported by experience. Phase One supported the predictions that adoption of the NMA was positively related to organisational recognition of research activity (legitimacy) and that the operation of the NMA was positively related to isomorphic pressures. However, these relations highlighted consistent uncertainty in the responses, and, on analysis, six inter-dependant factors were identified that showed that the authority and impact of the NMA was not straightforward. Thematic analysis of the Phase two qualitative data supported the first findings. In particular, this data emphasised how organisational decoupling between formal policies and actual organisational practices impacted the NMA influence.

Triangulation, because it harnesses the opportunity for harnessing affiliation between research methods, can create a richer outcome and identify issues that were not evident in either data collections on their own. The finding indicated the scale and complexity of adopting and practicing the new regulatory regime. Institutional Isomorphism provided a useful lens, in that it has identified three pressures on organisations, facing the same constraints, to develop similarities. However, in this situation, the isomorphic pressures were not the only pressures.

Thus, three issues have emerged from the triangulation, which are suggestive of the need for further study. They revolve around the growth of Australian research and development (Australian Government, National Health and Medical Research Council, & Department of Industry Innovation and Science, 2017) and the likelihood of the NMA impacting on stakeholders , within and external to the public sector.
The first relates to the need to understand the nature of the authority of the NMA. In this study, the NMA was examined in relation to participating public healthcare agencies,

which have a pre-existing relationship with government. However, health research involves multiple academic and business stakeholders, which raises the question of whether the authority of the NMA remains without the government association.

Following from the item raised above, a second question needs to be asked about how the competing cultural logics of different stakeholders should be managed. The third issue revolves around strategic ownership of the NMA in participating organisations.

8.12 Summary

The current chapter discussed the results and implications of the relationship between the National Mutual Acceptance (NMA), a government initiative to streamline the ethical review of multi-site clinical trials, and the research governance of Victorian public healthcare agencies. The propositions and hypotheses regarding the relationship between the NMA and agencies were based on the theory of Institutional Isomorphism. The complexity of this relationship first became apparent in the findings of Phase One data. Initially, it was anticipated that the differences between Applicant and Regulator roles would account for the differences in responses. To some extent, this was supported with indications that that Applicants were focussed on results and Regulators focussed on the processes around research governance. However, persistent uncertainty in responses indicated a need for further analysis.

Statistical analysis of Phase One data, using factor analysis and regression, identified six factors: Comparison with peers; Authority of the NMA; Endorsement of professional research governance standards; Reporting to the Board; Importance of the adoption of professional standards in research governance and Importance of NMA to hospital research regulation. Interrelationships between these factors and with participant demographics indicated firstly that that coercive, mimetic and normative influences were not independent of each other, but also that emphasis on local needs, rather than the national system, was significant in the impact of the NMA.

The second data set demonstrated how environmental constraints pushed organisations to focus on their individual needs, leading to a decoupling from the formal expectations of the NMA from the actual administrative processes. The dangers of decoupling

expected organisational compliance from actuality is repercussion on those "downstream" from that action. Decoupling has created a façade of legitimacy that has enabled institutionalisation singularity and precipitated a loss of legitimacy of the NMA. It has weakened the authority of the NMA and consequent inception of normative and mimetic influences.

Triangulation indicated a synergy between the data sets, which further suggested three issues in need for further study: the nature of NMA authority, competing cultural logics and ownership of the NMA. The summary, conclusions and scope for further research will be discussed in Chapter Nine.

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CHAPTER NINE:
CONCLUSIONS AND RECOMMENDATIONS

9.1 Introduction

This chapter summarised the discussion about the NMA impact on research of Victorian healthcare agencies. A short summary of the literature review, methodology, development of propositions, testing of propositions and results are presented, followed by the conclusions from the results discussed in the previous chapter. The chapter was structured as follows. Section 9.2 asks why research governance should be studied. Section 9.3 discusses the limitations of existing literature. Study context is summarised in Section 9.4, while Section 9.5 reviews the theoretical basis and Section 9.6 evaluates the conceptual model. Section 9.7 discuss the methodology of the study. Sections 9.8 and 9.9 present the perception of the current impact of the NMA and possible impact of the NMA in the future respectively, while Sections 9.10 and 9.11 present analysis and discussion of results and the address of the research question. Implications for theory are discussed in Section 9.12 while practical recommendations are outlined in Section 9.13. Section 9.14 discusses limitations of the thesis and the chapter concludes with Section 9.15.

9.2 Why study research governance?

This is a study of organisational research governance behaviour in response to the introduction of national system of single ethical review, the NMA. The NMA is a system whereby the outcome of single ethical review of multi-site projects is accepted by all the public sector sites participating in that project. The HRECs accredited to review for the NMA are situated in healthcare agencies and were already in existence when the NMA was introduced. A critical component of the national system is the concept of "downstream" or sites that accept the decision of a certified HREC. The acceptance is operationalised through the dedicated IT system, which is used to submit research projects for ethical or site specific consideration. The central tenet of this system is that this connection is trustworthy.

The study of governance involves not only what activities are involved but why those activities are important and the implications of bad or ineffective governance. Following the high profile corporate collapses of such as HIH insurance and One Tel in Australia, and Enron and WorldCom in the USA, many countries revised their regulatory approaches to improve corporate governance (Rebecca & Gørgens, 2009). For the past few decades, Australia has also undertaken significant corporate governance reforms (ASX Corporate Governance Council, 2007, 2014). Strong macro-economic reform and national productivity drivers have also led Australian governments to policy co-ordination between the different layers of governments (Australian Government, 2010; Bennett, 2013; Christensen & Lægreid, 2007). Thus, conceptually, the NMA is aligned with these developments.

History has recorded many incidents of inappropriate research projects that have initiated globally accepted ethical guidance (Gordon & Prentice 2000; Junod, 2014; Klitzman, 2011; Price, 2013). It also shows that understanding of research governance and what constitutes appropriate protection for research participants is not static, but has evolved over time in keeping with the current values of the era (Emanuel & Grady, 2006).

The current expectation in Australia is that responsibility for developing an effective governance framework of research falls to the organisations where the research is performed (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007). This framework is about ensuring the integrity of research (The National Health and Medical Research Council et al., 2007) and the mitigation of possible risks (Victorian Managed Insurance Authority, 2010, 2015). Traditionally mitigation has involved managing risks to those involved in the research, either as participants or involved in performing the research. Thus, guidance on research governance frameworks focus on the rights and responsibilities of those involved with a research project being undertaken within individual organisations.

As research increasingly involves regulatory compliance and external funding responsibilities, the various roles and responsibilities of those involved in research have become formalised (Shaw et al., 2005). The Australian system of managing multi-site trials involves a minimum of standard contracts between the organisation and trial

sponsor to ensure that the sites undertaking research and the research participants are indemnified against harm (Rallis Legal, 2014). Further guidance regarding responsible research practices has developed, such as the Good Clinical Practice Guidelines (GCP) which have now become integral to biomedical research.

9.3 Limitations of existing literature

The literature review, provided in Chapter Two, revealed that corporate governance literature is vast and diverse, highlighting the complexity of defining governance as a concept and providing multiple theoretical approaches to analysis (Cornforth, 2002; Hung, 1998). Definitions of corporate governance range from describing the processes and structures by which an organisation is directed and controlled (Cadbury, 2002) to a decision-making mechanism concerned with effective policy outcome (Edwards & Clough, 2005). Literature highlighted differences between the public and private sectors governance practices that arise because of the context in which its governance strategy is embedded (Armstrong et al., 2005). In particular, public sector agencies are compelled to comply with current government strategy in order to receive funds and other resources.

Literature exploring the nature of research governance has been more limited. Studies that report on the impact of review and oversight of research have referred to delays and associated costs (Salman et al., 2007; Webster & Temple-Smith, 2013; White et al., 2016). Clinical trial literature has described lack of transparency and inconsistent practices between relevant entities that impact the timeliness of start-and act as a disincentive to commercial partners (Clinical Trials Action Group, 2011; Health Outcomes International, 2015; Manville et al., 2013; NSW Ministry of Health, 2013). Although this a body of literature has expressed concern over difficulties experienced with research governance reviews, there is a dearth of literature exploring why Australian research governance personnel behave in ways that lead to difficulties for applicants.

Research governance refers to all the activities that affect the way clinical research is controlled and managed at a research site, but there are difference in how the scope of research activity is perceived. Within the Australian setting, the scope ranges from a

need to provide inter-organisational consistency (National Health and Medical Research Council, 2011b), to a subset of organisation's governance strategy (National Health and Medical Research Council & the Australian Research Council and Universities Australia, 2007; Victorian Managed Insurance Authority, 2010, 2015) and then to the activities involved in site specific assessment of research projects under consideration by the health care agency (Department of Health and Human Services, 2016).

As an alternative, UK literature describes research governance as a system responsibility (Shaw et al., 2005) and has indicated the likelihood of tensions when centralised models were introduced to supersede services that had been provide on a local level (Franck et al., 2004; Howarth et al., 2008). The literature identified that there might be variety in the conformity to the national model (decoupling) and that conformance might be stronger on organisational strategies and culture than on structures and processes (Ashworth et al., 2007).

These findings identified gaps in literature about how the Australian NMA was impacting on the research governance practices of participating healthcare agencies, and suggested a need to explore the roles and responsibilities of research governance personnel.

9.4 Study context

The context of this study, as outlined in Chapter Three, centred on the tension between the goals of the NMA and practices of the healthcare agencies participating in the NMA. The NMA is consistent with other national economic productivity agendas (Bennett, 2013; Loewenson, 2008). The focus of clinical trials reform in Australia aims to standardise and harmonise research administrative processes across agencies to better position Australia on the global market. .However, indicators of Victorian public healthcare agency performance are based on the output of individual healthcare agencies.

9.5 Theoretical basis

A critical analysis of the leading theories of corporate governance was undertaken. As this study explored the social aspect of governance and how structures, such as rules

and norms, become established, the theory of Institutional Isomorphism was employed to provide a theoretical basis to the collection and analysis of data. This theory suggests that the dynamic nature of environments plays a significant role in organisational decision-making. The study centred on a seminal publication by DiMaggio and Powell (1983) which identified three isomorphic mechanisms, coercive, mimetic and normative forces, as instrumental in inducing organisations, facing the same environmental constraints, to adopt similar structures and behaviours.

Institutional Isomorphism theorists propose that, for organisations to survive, they must appear successful or legitimate to their stakeholders. Isomorphism refers the tendency of organisations, under similar constraints, to develop similar processes or structure in order to appear legitimate (DiMaggio & Powell, 1983; Meyer & Rowan, 1977; Meyer & Scott 1983). Institutional theory was of value in the context of this study because it recognises the more resilient aspects of social structure and considers the processes by which organisations build and maintain structures, rules and norms. The model of isomorphic drivers of legitimacy, provided in Institutional theory, suggested that adoption of the NMA by healthcare agencies might not be simple.

9.6 Evaluation of the model

The conceptual model used in this study was designed for the purpose of this research. Three isomorphic influences from the theory of Institutional Isomorphism, together with perception of the importance of research to healthcare agencies, were paired with four pillars of performance measurement for clinical trials in order to determine the extent to which healthcare agencies engaged with the NMA. The consequent crossover of the theoretical and practical produced a conceptual model through which the influence of the NMA on healthcare agencies could be explored through measures of research governance efficiency.

The man weakness of this model is that it assumed a single link between the isomorphic drivers and endorsement of research governance efficiency. The study found multiple influences on research governance practices that acted against any influences of the NMA.

9.7 Methodology of the study

This was a field study, exploratory in nature, and the unit of analysis was Victorian public healthcare agencies. The study employed mixed methodology, an approach that combines quantitative and qualitative research methods in the same research inquiry to develop deeper insight into the association between the goals of the NMA and research governance practices. The data was collected sequentially, so that Phase One quantitative results informed the semi-structure interviews of Phase Two. Triangulation of the quantitative and qualitative data sets was used to corroborate and integrate them in a shared domain of empirical research and to provide a greater authority than that which comes from single method studies.

9.8 Perception of the current impact of the NMA

Findings on the impact of the NMA were ambiguous. While there was expectation that the NMA should provide coercive, mimetic and normative isomorphic influences that should influence agency practices, there was less confidence of the impact of the NMA as experienced. Many agencies practiced decoupling from the expected operating procedures. While these practices may have aligned their research review practices with their agencies' own internal expectations, it was problematic for those downstream. While decoupling is a recognised strategy in institutional theory to allow agencies to appear to adhere to inappropriate guidelines in order to preserve organisational efficiency (Boxenbaum & Jonsson, 2008; Meyer & Rowan, 1977), the creation of a "legitimacy facade" enables hidden activity and may lead to behaviours that precipitate a loss of external legitimacy (MacLean & Behnam, 2010). In this study, varying compliance to the operating procedures diminished the coercive impact of the NMA and a likelihood of personnel retaining a local focus.

9.9 Possible impact of the NMA in the future

Although participants agreed that the NMA is a reasonable component of multi-site research in public healthcare agencies, they noted different levels of engagement with the NMA throughout different sections of the agency. They identified limitations in the management of these variations as of critical importance, and made suggestions supporting the coercive pressure from the NMA.

9.10 Analysis and discussion of results

Analysis and discussion of the results highlighted the complexity of the association between the NMA and the healthcare agencies. Data collected in both phases indicated support for the NMA in principle, but the experiences of personnel involved with the NMA led to a lack of confidence in the system. Prevalence of local practices weakened the coercive force of the NMA, which limited development of cross-agency standardisation (normative isomorphism). Furthermore, participants discounted the usefulness of mimetic pressures because of the need to retain overall consistency. This finding was not consistent with the results from other studies applying Institutional Isomorphism as the theoretical base that found mimetic isomorphism to have the strongest influence (Frumkin & Galaskiewicz, 2004). Statistical analysis found interconnection between factors and demographics which was supportive of other theorists who describe the difficulty of separating isomorphic influences (Mizruchi & Fein 1999)

In all visualisations of the future of the NMA, the central tenet was the need for consistency across all parts of the NMA. As discussed in Chapter Eight, triangulation of the two data sets, developed a richer understanding of how the goals of the NMA intersect with the research governance practices of public healthcare agencies. This leads to a new challenge of enquiry articulated through the concepts of "authority", "competing cultural logistics" and "voice".

The first issue in this discussion relates to the quantification of the authority of the NMA. Factor analysis indicated that it was associated with recognition of the importance of research to the agency as well as involvement of external measures (Table 6.21). Other findings suggest that the NMA authority draws authority from being a government initiative in the public sector.

However, the study has identified competing cultural logistics between different stakeholders, highlighting the relevance of Deephouse's observation that perceptions of legitimacy vary depending on the audience (Deephouse, 1996). This study found differences between the goals of the national system and those of the participating

agencies, between jurisdictions and even between participating agencies. These differences were problematic because, not only do they fracture the connection between those involved in the NMA but they may produce risks that were not there in a single ethical system. This includes delays in research start up but may also enable institutionalisation of varying regulatory compliance.

Lack of "voice' was raised in both study phases and suggests a need to understand and weigh up the interests of key stakeholders when taking strategic decisions regarding the NMA. The concept of stakeholder engagement is an essential activity for the public sector and that stakeholder-related concepts of management and receptivity may inform strategic approaches are increasingly embedded in the 'business of businesses (Department of Health and Human Services, 2018). However, while this suggests a logical response to allowing stakeholder input, studies of stakeholder engagement frameworks describe the complexity of coordinating multiple viewpoints (Sinclair, 2010). Rather than focus on a general lack of transparency or consistency of research governance processes, this study indicates that the success of the NMA relates to the need to quantify the nature and scope of research governance roles, which is consistent with other study findings (Dunscombe, 2008; Kasule et al., 2016).

9.11 What influences organisations to comply with the National Mutual Acceptance?

This study addressed the question of what are the coercive, mimetic and normative pressures that influence public healthcare agencies in Victoria to comply with the National Mutual Acceptance.

The National Mutual Acceptance of single ethical review of multi-site research applies only to the publicly funded health sectors in Australia. It is a government initiative that requires all participating agencies to comply with standard operating procedures regarding the processes involved in research applications. This provides a coercive influence as all participating sites indicate similar behaviours in keeping with the guidance. However, the presence of decoupling from the formal activities to retain organisational specific processes weakened this coercive effect and diminished the capacity for mimetic or normative influences to develop.

While theory indicated linear association between the desire for legitimacy and the endorsement of specific behaviour, the reality of meeting specific expectations within the complexity of healthcare environments is not so straightforward. In this study, the main driver of similar organisational behaviours was found to be the coercive influence of the NMA that required all participating sites to engage with the dedicated IT system to manage multi-site research submissions. However, despite lack of cross-organisational influences found in the data collections, there were expectations that this should occur.

Literature has shown how the centralisation of existing services is likely to evoke different responses in those effected (Franck et al., 2004; Howarth et al., 2008) and the role for different avenues to support changes of organisational behaviours towards a new model (Ashworth et al., 2007). In particular, the role of leadership to initiate and sustain the momentum of change has emerged as critical.

These study findings highlighted lack of standardisation of practices and procedures around the NMA and the limited leadership engagement that eroded user trust of those personnel working in the system. This observation, in addition to the multiple associations between variables identified in the statistical analysis suggests is suggestive that underlying connections between isomorphic influences and behaviours might exist in more favourable circumstances.

9.12 Implications for theory

This study provides an original contribution to the body of knowledge around corporate governance, specifically that related to the governance of research. It raises questions around the nature of research governance and, especially the nature of organisational governance responsibilities within a national system. This would extend observations on quality assurance of research governance made in previous literature (Franck et al., 2004; Shaw et al., 2009) as well as observations made on decoupling from national requirements (Ashworth et al., 2007).

The limitations of this study to Victorian public healthcare agencies requires scholarly address because multi-site research encompasses a far broader scope including other

jurisdictions, private and not for profit healthcare, academia and commercial interests which adds further regulatory dimensions. Future aspects that should be further investigated might aim at understanding how single system of ethical review might apply to all research stakeholders, whether the conceptual model developed by this research apply to non-clinical trial research and whether reforms driven by government policy change have a higher rate of successful adoption and operation than reform resulting from other drivers.

Another implication for theory provided by this study relates to the dualistic position of research governance personnel. While the importance of the site specific assessment of the agency's capacity to perform that research project is accepted, little attention has been given to the personnel involved in research governance, how the tasks are performed or who makes the decision to authorise the study. The invisibility of research governance personnel was a significant factor understanding variations in research governance practices. Dunscombe (2008) claimed that ethics administrators were invisible because their tasks were considered part of the ethics committee processes and identified the need to establish the boundaries in which these roles operate. This suggests that recognition of the roles and responsibilities of other personnel involved with research administration would be incorporated into the activities of the organisation as a whole. This study capitalised on previous studies to suggest that further studies are required to understand where the authority for research governance decision-making is held and how it is influenced. Questions that could be pursued in relation to the clarity of research governance roles might include how the roles and responsibilities were of research governance personnel established and whether specific skills or expertise sought and if so what and why.

9.12.1.1 Implications for Institutional Isomorphism theory

The implications for Institutional Isomorphism theory from this research have made unique contributions to the extant knowledge. It has shown the importance of a strong coercive influence and the need to examine the environmental influence.

The study found that isomorphic influences are not distinct but impact as an interplay of coercive, mimetic and normative pressures, which is supportive of Mizruchi and Fein

(1999). While coercive impact of the NMA provided the strongest isomorphic influence, this was weakened by persistent organisational focus which created uncertainty. In institutional theory, times of uncertainty should lead to the development of mimetic pressures but this did not occur in this study. Instead, organisational governance practices remained disparate. Thus the findings did not support theory as promoted by DiMaggio and Powell (DiMaggio & Powell, 1983) and not did it support assertions that mimetic pressures are stronger in the public sector in times of ambiguity (Frumkin & Galaskiewicz, 2004).

This study found that ambiguity allowed the persistence of healthcare agency culture, which focused on the local needs of healthcare agencies and prevented a collective culture from emerging. This suggests that further study is required of leadership in changing organisational practices. Leadership in this context is multi-layered and needs to recognise the multi-faceted nature of organisational compliance to a national model. Through the lens of institutional isomorphism, this suggests that research into the relationship with research legitimacy in hospitals is critical.

The study also highlighted the need for further exploration of the environment on organisational practices. It demonstrated the need for agencies to perceive research governance of multi-site research within a broader system context and to recognise that the impact of their activities extends beyond their own organisational boundaries. This finding expanded on previous UK studies that explored difficulties associated with the introduction of centralised systems (Ashworth et al., 2007; Franck et al., 2004; Howarth et al., 2008) by examining research governance reforms in the Australian context. The Australian context provides further challenges because of the involvement of multiple jurisdictions as well as the involvement of other sectors such as non-public health, academic and business that are positioned within different legislative and regulatory frameworks. Logically, the principles of isomorphism should apply, but the findings of this study found otherwise, which suggests a need for research into government strategy to clarify influences that may affect Australia's economic performance in research and development.

9.13 Practical recommendations

In managing the future of the NMA, priority should be given to addressing factors that reinforce understanding of the authority of the NMA, address the "cultural clash" between different stakeholders and incorporate the stakeholder voice in determining how single ethical review can be achieved. These recommendations extend existing initiatives involving best practice in single ethical review l (National Health and Medical Research Council, 2016a) to identify and support the goals of the national system. Strategy must address NMA leadership, strengthening the knowledge base, developing a stakeholder engagement framework and opportunities to expand the NMA. These factors contribute independently to the NMA but also, as findings form the study show, factors related to the adoption of a national model interconnect to each other.

9.13.1 Leadership

Involvement of the leadership structure of the Board of Directors would provide significant impact on performance of the NMA. It is recommended that during any leadership discussions priority be given to developing a clear vision and communication of that vison, especially at organisational level.

- Develop the leadership capabilities of board members and senior management by extending their knowledge of the NMA. This includes identifying the external drivers impacting on adoption on the NMA, chiefly those related to improved accountability, efficiency and compliance with regulatory requirements
- Develop organisational capabilities so that personnel are able to prioritise the NMA goals rather than competing local requirements. Developing Board leadership skills entails enabling the organisation to improve decision making and service coordination in support of the Board.

9.13.2 Strengthen the knowledge base

It is recommended that during any discussions regarding strengthening the knowledge base around the NMA, priority be given to developing inter-organisational competencies rather than those of individual sites. This is particularly pertinent to understanding and quantifying the roles and responsibilities of research governance personnel.

9.13.3 Stakeholder engagement framework

Many participants felt they did not have a "voice" in the implementation of the NMA that allowed them to object to the requirements of the national system. This resulted in behaviour that restricted the operations of the NMA as they created "work arounds" or alternative processing. It is recommended that in any discussions around stakeholder engagement priority be given to the following:

- Create a stakeholder engagement framework to provide advice from a system-wide perspective
- Develop collaboration with stakeholders in the form that recognises the context in which they engage with the NMA
- Include representatives from peers and research partners, such as commercial interests, private healthcare and academia, as well as representation from public healthcare.

9.13.4 Development

Currently the NMA applies only to the public healthcare sectors of each jurisdiction, but multi-site research involves other sectors. These collaborations, such as those promoting medical and academic partnerships (for example, seeMonash Partners Academic Health Sciences Centre, 2015) could potentially promote alternate models of research review that could challenge the NMA concept. Thus, it is recommended that in any discussions pertaining to development of the NMA priority be given to the following:

- Creation of opportunities to broaden the NMA scope into private and not-for-public healthcare sectors
- Creation of opportunities to broaden the NMA scope into the academic sector.

9.14 Limitations of the thesis

A limitation of this study is that the scope of the study involved only those public healthcare agencies from a single state. There are inter-jurisdictional legislative and regulatory differences that potentially impact the undertaking and providing oversight of research (National Health and Medical Research Council, 2014c). While the decision to constrain data collection to Victoria may limit the translation of findings to other

settings, the involvement of differing regulatory requirements was considered to outweigh this limitation.

There were also theoretical limitations. Some of the institutional literature identified difficulties in distinguishing between different isomorphic pressures, (Mizruchi & Fein 1999) which, in this situation, meant that the measures could potentially capture more than one isomorphic pressure. In the survey, this meant restricting the scope of the items to one aspect of the pressure. For coercion pressures, the survey asked about the impact of the NMA on operations. Mimetic items focussed on comparison between organisations, which, in literature, preceded mimesis. The normative section of the survey was limited to standards. Despite this, study findings indicated connection between the isomorphic pressures and cannot support studies that supported specific influences, such as identification of the role of mimetic isomorphism (Frumkin & Galaskiewicz, 2004).

The quantitative data, collected in Phase One, was limited by low response rates to the survey which potentially could skew results. This was offset by the statistical analysis. The qualitative data collected in Phase Two was also limited in the number of interviews and that interviewees were limited in the time they could spare for interview. Use of triangulation facilitated the validation of data through cross verification from the two sources, to deepen the understanding and explanation of results.

The mechanism of data collection in this study are also open to criticism. There were also inherent restrictions through the use of an anonymous, electronic survey which prevented the number of potential respondents and the response rate from being known. Literature, however, suggests that respondents are more likely to respond more truthfully to sensitive items if they perceive their responses to be anonymous (Whelan, 2007). Use of voluntary participation raised issues of bias in the survey, because of the possibility that people who respond to an anonymous survey may hold strong views on the issues involved relative to those who did not respond.

Not all of those invited to participate in interviews agreed. This suggests a possibility that Phase Two interviews also might also lead to overrepresentation of particular opinion views. Furthermore, Phase Two data collection was limited by the overall

availability of research leaders who were only able to allocate time for one interview. Potentially, further discussion could have expanded on the issues raised in the interview.

It is acknowledged that the breath of analysis of this research may have prevented some of the depth and reliability of a single method. However, after reflection on the advantages and disadvantages of the methodology, it was considered that use of a mixed methods through a quantitate survey instrument and qualitative through semi-structured interview provided a capture of a unique moment in time and was the most effective and efficient means to collect data for this research.

9.15 Concluding remarks

Research reform in Australia is based on the principle that international research sponsors regard Australia as a single research destination. Australia's strategic priorities have been to rationalise research bureaucracy and harmonise research processes between entities. The NMA approach to single ethical review is an example of these strategies. The NMA is a system through which multiple healthcare agencies are required to collaborate with each other, for speed and consistency. In principle, these collaborations should benefit all those participating in the system, providing greater efficiency and less duplication. This study has identified that, despite the expectation of a single system, there were endemic variations in practices that led to uncertainty and lack of confidence.

A dominant influence on the creation of a single system stemmed from clinical trial reform initiatives to establish an optimal environment for clinical trial development, especially in regard to the timeliness of bureaucratic processes around research approval (Campion & Engwall, 2013; NSW Ministry of Health, 2013). The clinical trial industry has been a major influence on regulatory reform of the bureaucratic process around research review and on the development of the NMA. In contrast, the responsibilities of healthcare agencies to provide efficient health services that protect the safety of their service users in a cost effective manner, have led individual agencies to develop their own policies and procedures. This study has highlighted the social nature of the impact of the NMA on healthcare agencies and that there are three isomorphic elements,

coercive, mimetic and normative pressures, that are critical to the integration of the NMA into public healthcare practices.

The findings of this thesis align with UK literature (Ashworth et al., 2007; Franck et al., 2004; Howarth et al., 2008) which identified the types of challenges that arose when a centralised system replaced existing practices and previous calls for the invisibility of ethics administrators to be addressed (Dunscombe, 2008; Kasule et al., 2016).
To conclude, this study explored how the National Mutual Acceptance (NMA) model of single ethical review has currently impacted, and how it is likely to impact the future, of the research governance practices in public healthcare agencies participating in multi-site clinical trials. While it can found that the NMA does provide some coercive, mimetic and normative pressures on research governance decision-making, the study findings suggest there is need to strengthen these isomorphic pressures towards behaviours that are in keeping with clinical reform initiatives. It is hoped that this study will promote active debate regarding ongoing recognition of the NMA approach to single ethical review as an integral component of the contemporary research landscape. For the NMA to achieve its aims, it is critical that the nature and scope of research governance is understood by all key stakeholders.

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APPENDICES

11.1 APPENDIX A: Ethics approval

From: quest.noreply@vu.edu.au <quest.noreply@vu.edu.au>

Sent: Tuesday, 17 February 2015 3:16 AM

To: anona.armstrong@vu.edu.au

Cc: Bernice Davies; maree.fitzpatrick@vu.edu.au

Subject: Quest Ethics Notification - Application Process Finalised - Application Approved

Dear PROF ANONA ARMSTRONG,

Your ethics application has been formally reviewed and finalised.

» Application ID: HRE14-306

» Chief Investigator: PROF ANONA ARMSTRONG

» Other Investigators: DR MAREE FITZPATRICK, MS BERNICE DAVIES

» Application Title: Regulating the Regulators: Corporate Research Governance and National Mutual Acceptance

» Form Version: 13-07

The application has been accepted and deemed to meet the requirements of the National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research (2007)' by the Victoria University Human Research Ethics Committee. Approval has been granted for two (2) years from the approval date; 17/02/2015.

Continued approval of this research project by the Victoria University Human Research Ethics Committee (VUHREC) is conditional upon the provision of a report within 12 months of the above approval date or upon the completion of the project (if earlier). A report proforma may be downloaded from the Office for Research website at: http://research.vu.edu.au/hrec.php.

Please note that the Human Research Ethics Committee must be informed of the following: any changes to the approved research protocol, project timelines, any serious events or adverse and/or unforeseen events that may affect continued ethical acceptability of the project. In these unlikely events, researchers must immediately cease all data collection until the Committee has approved the changes. Researchers are also reminded of the need to notify the approving HREC of changes to personnel in research projects via a request for a minor amendment. It should also be noted that it is the Chief Investigators' responsibility to ensure the research project is conducted in line with the recommendations outlined in the National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research (2007).'

On behalf of the Committee, I wish you all the best for the conduct of the project.

Secretary, Human Research Ethics Committee
Phone: 9919 4781 or 9919 4461
Email: researchethics@vu.edu.au

11.2 APPENDIX B: Electronic invitations

Invitation email 1: First sent on the 17 August 2015.

Dear <First Name> <Last Name>

Please find an invitation to participate in research into multi-centred research. The survey will close on the 30th September 2015.

Invitation to a research governance survey

You are invited to participate in an anonymous survey on how hospitals govern research. The survey is part of a research project entitled: *Regulating the Regulators. Corporate Research Governance and National Mutual Acceptance*, being conducted as part of a PhD dissertation by student researcher Bernice Davies, under the supervision of Professor Anona Armstrong from the College of Law and Justice, Victoria University.

What am I being asked to do?

You can participate in this study at a number of levels:

Participate in the survey [link to survey] or copy and paste this URL into your internet browser: [link to survey]

Distribute this email to any personnel who might be interested in participating

Volunteer for an interview by emailing: Bernice.Davies@live.vu.edu.au

Do nothing. If you do not wish to participate, do not respond to this email.

Your participation is greatly appreciated.

Kind regards,

Bernice

Invitation email 2: First sent on the 06 September 2015.
Dear <First Name> <Last Name>

Recently I emailed you an invitation to participate in a research governance survey that I am undertaking as part of my PhD candidature. The survey will close shortly on the 30th September 2015. Please accept my thanks if you have already completed or intend to complete the survey.

The original email and links follow below.

Kind regards,
Bernice_____

ARCS weekly jobs and news bulletin

View this email in your browser

ARCS JOBS AND NEWS BULLETIN

ARCS AUSTRALIA
Professional Development in Therapeutics

Dear Joseph

RISK-BASED MONITORING SUMMIT - EARLY BIRD CLOSING TOMORROW!

When: 16 September 2015
Where: Kirribilli Club, Sydney

The Association of Clinical Research Professionals (ACRP) is the major global organisation supporting site and sponsor staff. Following on from ARCS signing a Memorandum of Understanding, ARCS is proud to announce the interim ACRP President, Ms Terri Hinkley will be flying out to join us for the 16 September Risk-Based Monitoring Summit in Kirribilli, Sydney. Join us for this must-attend event, book your place today.

What questions (or concerns) do you have about risk-based monitoring?
There will be a number of opportunities to have your queries addressed at the event. Submit your questions today by completing this short survey. If you include your details we will contact you after the event if your question was addressed.

MEMBER RENEWALS!

Time is running out to your renew your membership! We would love you to rejoin our association. Learn and network with 2,000 professionals committed to the sector and our leading association.

Please renew here or ring us on (02) 8905 0829 to renew over the phone.

11.3 APPENDIX C: Survey

11.3.1 Development of the survey instrument

The questionnaire was developed specifically for this project. It aimed to explore perceptions from those working in the Victorian research sector of whether the National Mutual Acceptance (NMA) scheme encouraged participating public health care services to develop similar behaviours. It was developed from the conceptual model presented in Figure 4.2.

Isomorphic Mechanisms

The survey sections were based on Institutional Isomorphism as presented by DiMaggio and Powell (1983) and the survey constructs were organisational field and coercive, mimetic and normative isomorphism.

NMA Legitimacy Drivers

Individual survey items were drawn from literature on Institutional Isomorphism (DiMaggio & Powell, 1983; Scott & Meyer, 1982) and governance principles (Armstrong, 2004; Australian National Audit Office, 2014; Barrett, 2003; Edwards & Clough, 2005) as well as the Victorian government NMA guidance (Victorian Department of Health and Human Services, 2013).

Demographics

Research participant demographics were also collected to provide a basis for comparison between groups by helping to define the population under study and reduce the possibility of a sampling bias or error

11.3.2 Section One: participant demographics

Common research participant demographics collected include age, gender, ethnicity, level of education, disabilities, employment, and socio-economic status as well as topic-specific characteristics. (American Psychological Association, 2010; Carmichael, 2016; Hammer, 2011). The

demographics collected in this questionnaire were: age, education, gender, role (Applicant or Regulator). Additionally, as organisational change literature suggested that predictors of attitude to organisational change included organisational level and years worked in current role, these items were also collected (Warr, 2008).

Organisational literature, especially that regarding worker characteristics and attitudes to change or job satisfaction, has found ambiguity in the way demographics influence behaviours. For example, the older workers are often perceived as having greater loyalty to their employing organisation but greater resistance to change (Centre of ageing and work, 2010). However, a review of literature has found age to be inconsistent predictor of attitudes and behaviours (Rhodes, 1983), which suggests that the study context needs to be considered. Hence, while employee differences have been shown to exist for a number of work values, attitudes and behaviours, there is limited knowledge of the causal factors associated with these differences (Vakola, Tsaousis, & Nikolaou, 2004). While employee values are important in both directly influencing employee behaviour and as significant moderators of research findings, these variations suggest that their influence may be situational and depend on the setting being investigated (Warr, 2008).

Due to the limitations of study sample, the original data intervals were regrouped to allow analysis to be undertaken.

Table 11.1 Demographics of research participants

Item	Interval	Analysis	Scale
Age	Under 20 /20-35 /35-50 /51-65 /Over 65	49 and under 50 and over	Interval
Education	Postgraduate Degree /Bachelor Degree /Advanced Diploma/ Diploma /Senior	Postgraduate Degree Bachelor Degree Non tertiary	Nominal

	Secondary Education (e.g. Year 12) /Other		
Gender	Male /Female /Prefer not to say	Male Female	Nominal
Role (occupation)	Researcher /research coordinator /Sponsor /Contract research organisation (CRO) /Regulator	Applicant Regulator	Nominal
Organisational level	Board /Senior management /Middle management /Non managerial/	Management/Non-management	Nominal
Years worked	Less than 1 /Between 1 and 5 /Between 6 and 10 /Over 10/	Less than 6 6 years and over	Interval

11.3.3 Likert scale

Likert scales were used to collect data in Sections Two and Three. Likert or frequency scales use fixed choice response formats to measure attitudes or opinions by measuring levels of agreement and disagreement (Bowling, 2002). A Likert scale assumes that the strength/intensity of experience is linear, such as on a continuum from strongly agree to strongly disagree, and makes the assumption that attitudes can be measured.

11.3.4 Section Two: the importance of research in public hospitals

Respondents' perception of the importance of research in hospitals was collected to establish whether research generated a field level interaction. Organisational fields are a central concept in Institutional Isomorphism as described by DiMaggio and Powell (1983) because they delineate the organisational activity in which isomorphic pressures are exerted. They also identify the key stakeholders of that activity and their roles which then creates socio-political connections (Scott, 2010).

The creation of an organisational field signifies that the activity is important enough to be recognised in its own right and not subsumed within other activities of that sector. Good governance of that activity should include both performance and accountability measures within a risk management framework (Australian National Audit Office (ANAO), 2014). Thus, if research is recognised as a distinct activity, organisations would be expected to establish relevant regulatory steps to ensure the activity is consistent with organisation's governance expectations.

The literature also suggests that perceptions of legitimacy might vary between stakeholders (Deephouse, 1996). Thus the questionnaire explored the perceptions of those from within the organisational field regarding the degree to which research should be a core healthcare services activity, or important enough to establish an organisational field; how this was regulated and the reality they observed.

Table 11.2: The importance of research in public hospitals

	Item	Interval	Analysis	Scale
Q1	How important is it that hospitals should regard research as a core activity?	Very important /Important /Neither Important nor Unimportant /Very Unimportant	Important Neither important nor unimportant Unimportant	Ordinal
Q2	All hospitals undertaking research must have written site policies and procedures	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q3	Research performance measures should be reported to the Board/senior management	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q4	Significant research issues (e.g. ethical breaches) should be reported to the Board/senior management	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q5	In general, hospitals do regard research as a core hospital activity	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal

11.3.5 Section three: isomorphic influences on site governance practice

Section Three addressed participant's perceptions of how the NMA impacted through coercive, mimetic and normative forces. Each sub-section addresses expectation of the importance of the National Mutual Acceptance (NMA) exerting an isomorphic force. Supporting statements were informed by the Victorian standard operating procedures (Department of Health & Human Services, 2015).

11.3.5.1 Coercive

According to DiMaggio and Powell, coercive pressures from the government greatly impact the public sector. This suggests that the NMA as a government initiative should be perceived as important by personnel within the public health research sector and that they would support research review behaviours that aligned with the national system.

Table 11.3: Survey items on the NMA as coercive influence

	Item	Interval	Analysis	Scale
Q6	How important should the National Mutual Acceptance (NMA) be to the way hospitals regulate their research?	Very important /Important /Neither Important nor Unimportant /Very Unimportant	Important Neither important nor unimportant Unimportant	Ordinal
Q7	Research authorisation should be as fast as possible	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q8	Hospital advice on how to apply for multisite research review should be consistent with NMA advice	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q9	Research governance managers should be encouraged to comply with NMA operating procedures	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q10	It should be the responsibility of senior hospital management to ensure that research complies with NMA targets	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q11	All research reviews should be undertaken with the same forms and processes	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q12	In general, the NMA is a powerful influence on hospital research governance	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal

Thus the questionnaire established perceptions of the importance of the NMA (Q6), before exploring how the organisation should adopt the NMA goals (Q7 and Q8), how the organisation should operationalise the NMA (Q9, Q10, Q11) and then the respondents' experience of the impact of the NMA (Q12).

11.3.5.2 Mimetic

In Institutional Isomorphism theory, mimetic isomorphism refers to the tendency of an organisation to imitate the structures and behaviours of a more successful peer. These pressures develop primarily when an organisation's goals or means of achieving these goals is unclear (DiMaggio & Powell, 1983). A specific goal of the NMA system is that approval of multi-site research is within the 60 day benchmark (Department of Health & Human Services, 2015). To determine whether certainty was significant, the first item of this set (Q13) asked participants to rank the importance of the NMA setting a standard approval time. Respondents then graded to the degree to which they agreed with the supporting items, opportunities for mimetic behaviour (Q14, Q15 and Q16), whether uncertainty increases the need for mimetic opportunity (Q17) and their experience of the NMA setting a standard time (Q18).

Table 11.4: Survey items on the NMA as mimetic influence

	Item	Interval	Analysis	Scale
Q13	How important is it for the NMA to set a standard time by which projects should be approved?	Very important /Important /Neither Important nor Unimportant /Very Unimportant	Important Neither important nor unimportant Unimportant	Ordinal
Q14	Research governance managers should have regular opportunity to network	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q15	To improve research authorisation times, research governance managers should first look to practices of other research offices	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal

Q16	When hospitals benchmark their research performance, they should compare to other like organisations	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q17	The ability to consult with other research governance managers is more important in times of change	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q18	The NMA does set a standard approval time	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal

11.3.5.3 Normative

Normative pressures are exerted through professional requirements, such as inter-organisational standards or education (DiMaggio & Powell, 1983). Operating guidance for organisations involved with the NMA emphasised the role of research governance (Department of Health & Human Services, 2015). Research governance standards were used in this sub-section of the survey as a proxy for normative pressure from the NMA.

Table 11.5: Survey items on the NMA as normative influence

	Item	Interval	Analysis	Scale
Q19	How important is it that there are professional standards in research governance?	Very important /Important /Neither Important nor Unimportant /Very Unimportant	Important Neither important nor unimportant Unimportant	Ordinal
Q20	Research governance staff should have common position descriptions and similar responsibilities	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q21	There should be a career path within research governance teams	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q22	Research governance staff should have agreed professional standards	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal
Q23	Research governance units do have professional standards	Strongly Agree /Agree /Neither Agree Nor Disagree /Disagree /Strongly Disagree	Agree Neither agree not disagree Disagree	Ordinal

To determine the importance of research governance standards, the first item of this set (Q19) asked participants to rank their importance. In keeping with current Australian guidance on career development (Career Industry Council of Australia, 2011), the next items explored support for common governance roles (Q20), standard development (Q21) and the expectation of research governance standards before asking respondents to rank their experiences of standards across governance units (Q23).

11.3.6 Section four: free text

Literature is divided on the use of open-ended text responses in questionnaires (O'Cathain & Thomas, 2004). In this situation, they were included to identify further issues for exploration in Phase Two of the study:

- What systems, processes or initiatives have you encountered (or implemented) that assist research review or oversight?
- What major difficulties have you encountered in the research review process? How would you resolve these?
- Would you like to make any other comments?

The responses were thematically analysed and presented following statistical analysis.

Invitation to complete a survey about hospitals and multi-centred research

You are invited to participate in an anonymous survey about hospitals and multi-centred research. The data from this survey will be analysed as part of PhD research by Bernice Davies entitled

Regulating the Regulators: Corporate Research Governance and National Mutual Acceptance.

We estimate the survey should take no longer than 10 minutes to complete. There are no right or wrong answers. Please note that by completing the survey you are consenting to the information you provide being included in the data analysis of this study.

I will also be conducting interviews following an analysis of the survey data. If you are interested in participating in an interview, please contact me.

Ethics

This survey has been approved by the Victorian University Human Research Ethics Committee. The completed surveys will be securely stored and available only to my supervisors and me. Survey results will only be used in aggregate form; your anonymity and the confidentiality of your responses are assured. Aggregate data may also be made available to future researchers through the Victorian University Repository.

Queries and complaints

If you have any queries, please contact my supervisor Professor Anona Armstrong, College of Law and Justice, on 03 99196155; or email: Anona.Armstrong@vu.edu.au. If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email Researchethics@vu.edu.au or phone (03) 9919 4781 or 4461.

If you wish to discuss the survey or would like to participate in an interview, please contact me, Ms Bernice Davies, PhD Candidate, College of Law and Justice, Victoria University on mobile: 0406518081 or email Bernice.Davies@live.vu.edu.au.

Thank you for participating. I welcome your thoughts

SECTION ONE: ABOUT YOURSELF

Please tick the box representing the most appropriate response for you in respect of the following items.

Your age (years)

- ○ Under 20
- ○ 20-35
- ○ 35-50
- ○ 51-65
- ○ Over 65

Your highest completed level of education

- ○ Postgraduate Degree
- ○ Bachelor Degree
- ○ Advanced Diploma/ Diploma
- ○ Senior Secondary Education (e.g. Year 12)
- ○ Other (Please specify)

Your gender

- ○ Male
- ○ Female
- ○ Prefer not to say

Your main role

- ○ Researcher /research coordinator
- ○ Sponsor /Contract research organisation (CRO)
- ○ Research governance (including ethics, business, legal etc.)
- ○ Other (please specify

Your level within your organisation

- ○ Board
- ○ Senior management
- ○ Middle management
- ○ Non managerial
- ○ Other (Please specify)

Years worked in your current role

- ○ Less than 1
- ○ Between 1 and 5
- ○ Between 6 and 10
- ○ Over 10

Your State or Territory

- ○ Victoria
- ○ New South Wales
- ○ Australian Capital Territory
- ○ Queensland
- ○ Northern Territory
- ○ Western Australia
- ○ South Australia
- ○ Tasmania

SECTION TWO: THE IMPORTANCE OF RESEARCH IN PUBLIC HOSPITALS

This section explores your view on how hospitals regard the role of research in health care. There are no right or wrong answers.
To what extent is the following important?

	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
How important is it that hospitals should regard research as a core activity?	○	○	○	○	○

To what extent do you agree with the following statements?

	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
All hospitals undertaking research must have written site policies and procedures	○	○	○	○	○
Research performance measures should be reported to the Board/senior management	○	○	○	○	○
Significant research issues (e.g. ethical breaches) should be reported to the Board/senior management	○	○	○	○	○
In general, hospitals do regard research as a core hospital activity	○	○	○	○	○

SECTION THREE: INFLUENCES ON SITE GOVERNANCE PRACTICE
To what extent is the following important?

	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
How important should the National Mutual Acceptance (NMA) be to the way hospitals regulate their research?	○	○	○	○	○

To what extent do you agree with the following statements?

	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
Research authorisation should be as fast as possible	○	○	○	○	○
Hospital advice on how to apply for multi-site research review should be consistent with NMA advice	○	○	○	○	○
Research governance managers should be encouraged to comply with NMA operating procedures	○	○	○	○	○
It should be the responsibility of senior hospital management to ensure that research complies with NMA targets	○	○	○	○	○
All research reviews should be undertaken with the same forms and processes	○	○	○	○	○
In general, the NMA is a powerful influence on hospital research governance	○	○	○	○	○

To what extent is the following important?

	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
How important is it for the NMA to set a standard time by which projects should be approved?	○	○	○	○	○

To what extent do you agree with the following statements?

	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
Research governance managers should have regular opportunity to network	○	○	○	○	○
To improve research authorisation times, research governance managers should first look to practices of other research offices	○	○	○	○	○
When hospitals benchmark their research performance, they should compare to other like organisations	○	○	○	○	○
The ability to consult with other research governance managers is more important in times of change	○	○	○	○	○
The NMA does set a standard approval time	○	○	○	○	○

To what extent is the following important?

	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
How important is it that there are professional standards in research governance?	○	○	○	○	○

To what extent do you agree with the following statements?

	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
Research governance staff should have common position descriptions and similar responsibilities	○	○	○	○	○
There should be a career path within research governance teams	○	○	○	○	○
Research governance staff should have agreed professional standards	○	○	○	○	○
Research governance units do have professional standards	○	○	○	○	○

SECTION FOUR: YOUR EXPERIENCE OF RESEARCH GOVERNANCE PRACTICES

In this section we are asking for your own experiences of site specific assessment

What systems, processes or initiatives have you encountered (or implemented) that assist research review or oversight?

What major difficulties have you encountered in the research review process? How would you resolve these?

Would you like to make any other comments?

11.4 APPENDIX D: Survey response categories

Table 11.6: Survey response categories

Demographics						
ID	**Item**	**Ranking**				
	Age (years)	Under 20	20-35	35-50	51-65	Over 65
	Highest completed level of education	Postgraduate Degree	Bachelor Degree	Advanced Diploma/ Diploma	Senior Secondary Education	Other
	Gender	Male	Female	Prefer not to say		
	Main role	Researcher /research coordinator	Sponsor /Contract research organisation (CRO)	Research governance (including ethics, business, legal etc)	Other	
	Level within your organisation	Board	Senior management	Middle management	Non managerial	Other
	Years worked in current role	Less than 1	Between 1 and 5	Between 6 and 10	Over 10	
	State					
The importance of research in public hospitals						
ID	**Item**	**Ranking**				
1	How important is it that hospitals should regard research as a core activity?	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
2	All hospitals undertaking research must have written site policies and procedures	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
3	Research performance measures should be reported to the Board/senior management	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	
4	Significant research issues (e.g. ethical breaches) should be reported to the Board/senior management	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
5	In general, hospitals do regard research as a core hospital activity	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
Coercive influence						
ID	**Item**	**Ranking**				

6	How important should the National Mutual Acceptance (NMA) be to the way hospitals regulate their research?	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
7	Research authorisation should be as fast as possible	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
8	Hospital advice on how to apply for multi-site research review should be consistent with NMA advice	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	
9	Research governance managers should be encouraged to comply with NMA operating procedures	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
10	It should be the responsibility of senior hospital management to ensure that research complies with NMA targets	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
11	All research reviews should be undertaken with the same forms and processes	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
12	In general, the NMA is a powerful influence on hospital research governance	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree

Mimetic Influence

ID	Item	Ranking				
13	How important is it for the NMA to set a standard time by which projects should be approved?	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
14	Research governance managers should have regular opportunity to network	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
15	To improve research authorisation times, research governance managers should first look to practices of other research offices	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree

16	When hospitals benchmark their research performance, they should compare to other like organisations	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
17	The ability to consult with other research governance managers is more important in times of change	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
18	The NMA does set a standard approval time	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree

Normative Influence

ID	Item	Ranking				
19	How important is it that there are professional standards in research governance?	Very important	Important	Neither Important nor Unimportant	Unimportant	Very Unimportant
20	Research governance staff should have common position descriptions and similar responsibilities	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
21	There should be a career path within research governance teams	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
22	Research governance staff should have agreed professional standards	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree
23	Research governance units do have professional standards	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree

Your experience of research governance practices	
	What systems, processes or initiatives have you encountered (or implemented) that assist research review or oversight?
	What major difficulties have you encountered in the research review process? How would you resolve these?
	Would you like to make any other comments?

11.5 APPENDIX E: Importance of Research

Descriptive Statistics

Table 11.7: Frequency and distribution of importance of research

	Important	Neither Important nor important	Unimportant	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
2.1: How important is it that hospitals should regard research as a core activity?	98%(147)	1%(2)	0%(0)	100%(149)	0%(0)

	Agree	Neither agree nor disagree	Disagree	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
2.2: All hospitals undertaking research must have written site policies and procedures	99%(148)	1%(1)	0%(0)	100%(149)	0%(0)
2.3: Research performance measures should be reported to the Board/senior management	81%(121)	17%(26)	1%(2)	100%(149)	0%(0)
2.4: Significant research issues (e.g. ethical breaches) should be reported to the Board/senior management	83%(124)	15%(22)	2%(3)	100%(149)	0%(0)
2.5: In general, hospitals do regard research as a core hospital activity	16%24)	14%(21)	69%(102)	99%(147)	1%(2)

11.6 APPENDIX F: Results coercive isomorphism

Descriptive Statistics

Table 11.8 Frequency and distribution of Coercive items

	Important	Neither important nor unimportant	Unimportant	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
3.1: How important should the National Mutual Acceptance (NMA) be to the way hospitals regulate their research?	89%(131)	9%(13)	2%(3)	99%(147)	1%(2))

	Agree	Neither agree nor disagree	Disagree	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
3.2: Research authorisation should be as fast as possible	95%(142)	4%(6)	1%(1)	100%(149)	0%(0)
3.3: Hospital advice on how to apply for multi-site research review should be consistent with NMA advice	95%(140)	5%(7)	1%(1)	99%(148)	1%(1)
3.4 Research governance managers should be encouraged to comply with NMA operating procedures	93%(138)	7%(11)	0%(0)	100%(149)	0%(0)
3.5:It should be the responsibility of senior hospital management to ensure that research complies with NMA targets	76%(112)	18%(27)	6%(9)	99%(148)	1%(1)

3.6: All research reviews should be undertaken with the same forms and processes	64%(96)	30%(44)	6%(9)	100%(149)	0%(0)
3.7:In general, the NMA is a powerful influence on hospital research governance	44%(66)	46%(68)	10%(15)	100%(149	0%(0)

11.7 APPENDIX G: Results mimetic isomorphism

Descriptive Statistics

Table 11.9 Frequency and distribution of Mimetic items

	Important	Neither Important nor unimportant	Unimportant	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
4.1: How important is it for the NMA to set a standard time by which projects should be approved?	94% (140)	5% (7)	1%(2)	100% (149)	0%(0)

	Agree	Neither Agree Nor Disagree	Disagree	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
4.2: Research governance managers should have regular opportunity to network	85%(127)	14%(21)	1%(1)	100%(149)	0%(0)
4.3: To improve research authorisation times, research governance managers should first look to practices of other research offices	72% (107)	25%(36)	4%(6)	100%(149)	0%(0)
4.4: When hospitals benchmark their research performance, they should compare to other like organisations	87%(129)	13%(19)	1%(1)	100%(149)	0%(0)
4. 5: The ability to consult with other research governance	78%(115)	22%(32)	1%(1)	99%(148)	1%(1)

managers is more important in times of change					
4. 6: The NMA does set a standard approval time	69%(100)	26%(37)	5%(7)	97%(144)	3%(3)

11.8 APPENDIX H: Results normative isomorphism

Descriptive Statistics

Table 11.10: Frequency and distribution of normative items

	Important	Neither Important nor unimportant	Unimportant	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
5.1: How important is it that there are professional standards in research governance?	95%(141)	5%(7)	0%(0)	99%(148)	1%(1)

	Agree	Neither agree nor disagree	Disagree	Total	Missing
	%(Freq)	%(Freq)	%(Freq)	%(Freq)	%(Freq)
5.2: Research governance staff should have common position descriptions and similar responsibilities	75%(112)	24%(36)	1%(1)	100%(149)	0%(0)
5.3: There should be a career path within research governance teams	69%(103)	30%(45)	1%(1)	100%(149)	0%(0)
5.4: Research governance staff should have agreed professional standards	81%(120)	19%(29)	0%(0)	100%(149)	0%(0))
5.5: Research governance units do have professional standards	31%(46)	54%(81)	15%(22)	100%(149)	0%(0)

11.9 APPENDIX I: Phase One respondents

Table 11.11: List of Phase One responder demographics

ID	Age	Education	Gender	Role	Level	Years in role
1	51 to 65	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
2	35 to 50	Diploma	Female	Regulator	Non-managerial	6 to 10
3	51 to 65	Post Grad	Female	Regulator	Senior management	>10
4	35 to 50	Bachelor	Female	Regulator	Middle management	1 to 5
5	51 to 65	Post Grad	Female	Regulator	Middle management	6 to 10
6	51 to 65	Bachelor	Female	Regulator	Middle management	6 to 10
7	35 to 50	Post Grad	Female	Researcher /coordinator	Non-managerial	>10
8	35 to 50	Bachelor	Female	Regulator	Senior management	>10
9	35 to 50	Post Grad	Male	Regulator	Middle management	6 to 10
10	51 to 65	Post Grad	Female	Researcher /coordinator	Non-managerial	1 to 5
11	35 to 50	Post Grad	Female	Regulator	Non-managerial	1 to 5
12	35 to 50	Bachelor	Female	Regulator	Non-managerial	1 to 5
13	35 to 50	Post Grad	Male	Regulator	Non-managerial	1 to 5
14	35 to 50	Bachelor	Female	Sponsor/CRO	Middle management	>10
15	51 to 65	Post Grad	Female	Regulator	Middle management	6 to 10
16	51 to 65	Bachelor	Female	Researcher /coordinator	Non-managerial	>10
17	35 to 50	Other	Male	Researcher /coordinator	Middle management	<1
18	35 to 50	Diploma	Female	Researcher /coordinator	Middle management	1 to 5
19	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10
20	20 to 34	Post Grad	Female	Regulator	Middle management	6 to 10
21	35 to 50	Post Grad	Female	Regulator	Middle management	>10
22	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	6 to 10

23	35 to 50	Bachelor	Female	Regulator	Non-managerial	1 to 5
24	51 to 65	Post Grad	Male	Researcher /coordinator	Senior management	6 to 10
25	35 to 50	Post Grad	Male	Researcher /coordinator	Middle management	1 to 5
26	35 to 50	Post Grad	Female	Researcher /coordinator	Non-managerial	1 to 5
27	51 to 65	Bachelor	Female	Regulator	Non-managerial	1 to 5
28	35 to 50	Post Grad	Female	Researcher /coordinator	Non-managerial	1 to 5
29	35 to 50	Bachelor	Female	Regulator	Non-managerial	1 to 5
30	20 to 34	Bachelor	Female	Regulator	Non-managerial	6 to 10
31	20 to 34	Bachelor	Female	Regulator	Non-managerial	1 to 5
32	>65	Post Grad	Male	Regulator	Other (eg contractor)	1 to 5
33	20 to 34	Bachelor	Female	Regulator	Non-managerial	1 to 5
34	20 to 34	Bachelor	Male	Sponsor/CRO	Non-managerial	6 to 10
35	35 to 50	Post Grad	Female	Researcher /coordinator	Senior management	1 to 5
36	51 to 65	Post Grad	Female	Regulator	Non-managerial	6 to 10
37	35 to 50	Post Grad	Female	Regulator	Senior management	1 to 5
38	20 to 34	Post Grad	Female	Sponsor/CRO	Middle management	6 to 10
39	35 to 50	Secondary	Female	Sponsor/CRO	Middle management	1 to 5
40	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
41	20 to 34	Post Grad	Female	Regulator	Non-managerial	<1
42	35 to 50	Bachelor	Female	Researcher /coordinator	Middle management	1 to 5
43	20 to 34	Post Grad	Female	Researcher /coordinator	Non-managerial	1 to 5
44	20 to 34	Bachelor	Male	Regulator	Non-managerial	1 to 5
45	51 to 65	Bachelor	Female	Researcher /coordinator	Middle management	>10
46	20 to 34	Post Grad	Male	Researcher /coordinator	Middle management	6 to 10
47	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
48	51 to 65	Diploma	Male	Regulator	Middle management	>10
49	35 to 50	Post Grad	Female	Regulator	Senior management	1 to 5

50	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	6 to 10
51	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	<1
52	20 to 34	Bachelor	Female	Regulator	Non-managerial	1 to 5
53	20 to 34	Post Grad	Male	Researcher /coordinator	Non-managerial	1 to 5
54	20 to 34	Bachelor	Female	Sponsor/CRO	Middle management	1 to 5
55	20 to 34	Bachelor	Female	Sponsor/CRO	Middle management	6 to 10
56	35 to 50	Post Grad	Female	Sponsor/CRO	Middle management	<1
57	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
58	20 to 34	Bachelor	Female	Researcher /coordinator	Middle management	6 to 10
59	35 to 50	Bachelor	Female	Sponsor/CRO	Middle management	1 to 5
60	35 to 50	Bachelor	Female	Sponsor/CRO	Non-managerial	1 to 5
61	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
62	20 to 34	Bachelor	Male	Researcher /coordinator	Non-managerial	1 to 5
63	35 to 50	Bachelor	Female	Regulator	Non-managerial	>10
64	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
65	35 to 50	Bachelor	Male	Researcher /coordinator	Middle management	6 to 10
66	51 to 65	Diploma	Male	Researcher/coordinator	Non-managerial	>10
67	20 to 34	Bachelor	Male	Researcher /coordinator	Non-managerial	1 to 5
68	51 to 65	Post Grad	Male	Researcher /coordinator	Senior management	>10
69	20 to 34	Post Grad	Female	Regulator	Non-managerial	1 to 5
70	35 to 50	Bachelor	Female	Regulator	Middle management	1 to 5
71	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	>10
72	51 to 65	Post Grad	Female	Regulator	Middle management	>10
73	51 to 65	Post Grad	-99	Researcher/coordinator	Other (eg contractor)	6 to 10

74	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	>10
75	35 to 50	Bachelor	Male	Regulator	Middle management	6 to 10
76	51 to 65	Diploma	Female	Regulator	Other (eg contractor)	>10
77	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
78	51 to 65	Bachelor	Female	Regulator	Non-managerial	>10
79	35 to 50	Bachelor	Female	Sponsor/CRO	Middle management	>10
80	51 to 65	Post Grad	Female	Researcher /coordinator	Non-managerial	>10
81	51 to 65	Bachelor	Female	Researcher /coordinator	Non-managerial	>10
82	20 to 34	Post Grad	Female	Regulator	Non-managerial	1 to 5
83	35 to 50	Bachelor	Male	Researcher /coordinator	Non-managerial	1 to 5
84	20 to 34	Bachelor	Male	Researcher /coordinator	Non-managerial	1 to 5
85	35 to 50	Bachelor	Male	Sponsor/CRO	Middle management	6 to 10
86	51 to 65	Post Grad	Male	Researcher /coordinator	Non-managerial	>10
87	20 to 34	Post Grad	Male	Researcher /coordinator	Non-managerial	6 to 10
88	20 to 34	Post Grad	Male	Researcher /coordinator	Middle management	6 to 10
89	51 to 65	Bachelor	Male	Researcher /coordinator	Middle management	>10
90	35 to 50	Bachelor	-99	Researcher /coordinator	Middle management	6 to 10
91	20 to 34	Bachelor	Male	Researcher /coordinator	-99	1 to 5
92	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
93	35 to 50	Bachelor	Female	Sponsor/CRO	Non-managerial	1 to 5
94	35 to 50	Bachelor	Female	Sponsor/CRO	Middle management	6 to 10
95	51 to 65	Bachelor	Male	Researcher /coordinator	Senior management	>10
96	35 to 50	Post Grad	Female	Researcher /coordinator	Middle management	>10

97	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	6 to 10
98	51 to 65	Diploma	Female	Researcher /coordinator	Non-managerial	6 to 10
99	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	6 to 10
100	51 to 65	Secondary	Female	Researcher /coordinator	Non-managerial	>10
101	35 to 50	Bachelor	Male	Researcher /coordinator	Non-managerial	6 to 10
102	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5
103	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10
104	51 to 65	Bachelor	Male	Researcher /coordinator	Middle management	6 to 10
105	35 to 50	Post Grad	Female	Researcher /coordinator	Non-managerial	6 to 10
106	35 to 50	Bachelor	Female	Regulator	Middle management	6 to 10
107	51 to 65	Bachelor	Female	Regulator	Non-managerial	>10
108	20 to 34	Secondary	Female	Regulator	Non-managerial	1 to 5
109	51 to 65	Bachelor	Male	Researcher/coordinator	Middle management	>10
110	20 to 34	Post Grad	Female	Researcher /coordinator	Other (eg contractor)	1 to 5
111	35 to 50	Diploma	Female	Regulator	Non-managerial	6 to 10
112	35 to 50	Bachelor	Female	Regulator	Non-managerial	1 to 5
113	35 to 50	Bachelor	Female	Regulator	Non-managerial	1 to 5
114	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	6 to 10
115	35 to 50	Post Grad	Female	Researcher /coordinator	Middle management	6 to 10
116	20 to 34	Bachelor	Female	Researcher /coordinator	Non-managerial	6 to 10
117	35 to 50	Diploma	Female	Regulator	Other (eg contractor)	>10
118	35 to 50	Bachelor	Female	Sponsor/CRO	Non-managerial	6 to 10
119	51 to 65	Post Grad	Male	Researcher /coordinator	Senior management	>10
120	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10

121	20 to 34	Post Grad	Female	Researcher /coordinator	Non-managerial	<1
122	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10
123	>65	Post Grad	Male	Researcher /coordinator	Non-managerial	>10
124	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10
125	51 to 65	Bachelor	Female	Regulator	Non-managerial	6 to 10
126	35 to 50	Post Grad	Female	Regulator	Middle management	6 to 10
127	35 to 50	Bachelor	Female	Regulator	Middle management	>10
128	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10
129	35 to 50	Bachelor	Male	Researcher /coordinator	Middle management	6 to 10
130	35 to 50	Post Grad	Male	Researcher /coordinator	Middle management	6 to 10
131	35 to 50	Bachelor	Female	Regulator	Non-managerial	>10
132	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10
133	35 to 50	Bachelor	Female	Researcher /coordinator	Non-managerial	6 to 10
134	51 to 65	Bachelor	Female	-99	Non-managerial	>10
135	35 to 50	Diploma	Female	Researcher /coordinator	Non-managerial	1 to 5
136	20 to 34	Bachelor	Male	Researcher /coordinator	Non-managerial	1 to 5
137	35 to 50	Bachelor	Female	Regulator	Non-managerial	6 to 10
138	20 to 34	Post Grad	Female	Researcher /coordinator	Non-managerial	6 to 10
139	35 to 50	Post Grad	Female	Regulator	Middle management	1 to 5
140	35 to 50	Bachelor	Female	Regulator	Non-managerial	>10
141	35 to 50	Bachelor	Male	Regulator	Non-managerial	1 to 5
142	35 to 50	Bachelor	Female	Regulator	Middle management	6 to 10
143	20 to 34	Post Grad	Female	Researcher /coordinator	Non-managerial	1 to 5
144	20 to 34	Bachelor	Female	Researcher/coordinator	Other (eg contractor)	1 to 5
145	20 to 34	Post Grad	Female	Researcher /coordinator	Middle management	1 to 5
146	51 to 65	Bachelor	Female	Researcher /coordinator	Non-managerial	1 to 5

147	35 to 50	Bachelor	Male	Researcher /coordinator	Non-managerial	1 to 5
148	20 to 34	Secondary	Male	Researcher/coordinator	Other (eg contractor)	<1
149	20 to 34	Post Grad	Female	Researcher/coordinator	Senior management	<1

11.10 APPENDIX J: Participant information

INFORMATIONTO PARTICIPANTS INVOLVED IN RESEARCH

You are invited to participate

You are invited to participate in a research project entitled*: Regulating the Regulators: Corporate Research Governance and National Mutual Acceptance*. This project is being conducted by a student researcher Bernice Davies as part of a PhD dissertation, under the supervision of Professor Anona Armstrong from the College of Law and Justice, Victoria University.

Project explanation

The National Mutual Acceptance (NMA) is a national system of research review that was implemented in 2013 to facilitate single ethical and scientific review of multi-centre clinical research across participating Australian jurisdictions. There has been limited discussion on how the governance of research in hospitals has been affected by this introduction. Research governance refers to how the hospitals oversee the research in which they are involved, including the structures and processes used to ensure responsible research conduct. Our study aims to determine what influences the governance of clinical research in Victorian hospitals and what models of research governance best address the implications of the NMA.

What will I be asked to do?

You are being invited to an interview to discuss what effective research governance looks like and what likely future developments in the field might entail.

Your participation in this study will involve a single interview. With your permission, the interview will be audio taped and should take no longer than one hour. Examples of the interview questions may include:

- Do you think that hospital Boards or senior management consider research as a core hospital activity?
- Is there a link between the NMA and individual hospital governance practices? If so what is the link?

You will also be asked to provide some brief demographic data such as your role and level of experience. The interview will be transcribed and all identifiers, including your name, will be replaced by pseudonyms. The transcription of your interview will be made available to you, if you wish to read it before it analysed. You are encouraged to correct the transcript, if you wish. Only the research team will access the raw data but excerpts from the interviews will be used to support claims in Bernice's thesis or any publications from this study. These excerpts will be identified by a pseudonym.

What will I gain from participating?

It is unlikely that you will gain benefits directly from participating in this research project, but the information you provide may inform the development of strategies or new research in the future.

How will the information I give be used?

The information will be used towards a PhD but may also be used in an article offered for publication, a conference presentation and may also be made available to future researchers through the Victorian University Repository, if you agree. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. If you wish to your name included as a contributor, to the data please indicate on the consent form.

What are the potential risks of participating in this project?

While we don't anticipate any major risks from participating in this project, we are aware of the importance of maintaining your privacy and the confidentiality of your responses. You may experience embarrassment if someone was able to identify you through your responses, hence all care will be taken to disguise your identity and pseudonyms will be used in place of any name mentioned. If you feel that some of the questions we ask are stressful or upsetting or if you do not wish to answer a question, you may skip it and go

to the next question, or you may stop immediately. If you do become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

How will this project be conducted?

The interview will take up to 60 minutes. With your permission, it will be audio taped. You will be allocated a pseudonym in the transcript of the interview.

At the completion of the study, the research data will be stored in Professor Armstrong's office for 5 years. Computer files will be password protected.

Who is conducting the study?

The project will be conducted at Victoria University by:

Principal Investigator

Professor Anona Armstrong, College of Law and Justice,

Phone: 03 99196155;

Email: Anona.Armstrong@vu.edu.au.

Student

Bernice Davies**,** College of Law and Justice,

Phone 0406518081
Email**:** bernice.davies@live.vu.edu.au

Any queries about your participation in this project may be directed to the Principal Investigator listed above.

If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.auor phone (03) 9919 4781 or 4461.

11.11 APPENDIX K: Participant consent

CONSENT FORM FOR PARTICIPANTS INVOLVED IN RESEARCH

INFORMATION TO PARTICIPANTS:
We would like to invite you to be a part of a study about the governance of research in Victorian public hospitals. The study aims to determine what influences Victorian hospitals to adopt practices in corporate governance of clinical research and what models of research governance best address the implications of the NMA. You are invited to participate in an audio taped interview up to 60 minutes in a time and place suitable to you. All care will be taken to disguise your identity and pseudonyms will be used in place of any name mentioned, but you are encouraged to review and amend the transcript of the interview if you wish.

CERTIFICATION BY SUBJECT

I, .
(Name)

of .
(Address)

certify that I am at least 18 years old* and that I am voluntarily giving my consent to participate in the study:

Re*gulating the Regulators*: Corporate Research Governance and National Mutual Acceptance,

being conducted at Victoria University by Professor Anona Armstrong from College of Law and Justice.

I certify that the objectives of the study, together with any risks and safeguards associated with the procedures listed hereunder to be carried out in the research, have been fully explained to me by the student:

Bernice Davies

Phone 0406518081 Email: bernice.davies@live.vu.educ.au

and that I freely consent to participation involving the below mentioned procedures:

☐ audio taped interview of about 60 minutes
☐ that aggregated data from this interview may be shared in the VU repository

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this study at any time and that this withdrawal will not jeopardise me in any way. In addition,

☐ I wish my name listed as a contributor in the thesis

I have been informed my identity will be kept confidential.

Signed:

Date:

Any queries about your participation in this project may be directed to the researcher

Professor Anona Armstrong, College of Law and Justice,

Phone: 03 99196155; Email: Anona.Armstrong@vu.edu.au.

If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email Researchethics@vu.edu.au or phone (03) 9919 4781 or 4461.

[*please note: Where the participant/s are aged under 18, separate parental consent is required; where the participant/s are unable to answer for themselves due to mental illness or disability, parental or guardian consent may be required.]

[Participant consent V 08.01.2015]

11.12 APPENDIX L: Interview schedule

1	**What is your understanding of the National Mutual Acceptance (NMA) or national model of single ethical review of multi-site clinical trials?**	
	1.1	Has your vision been achieved? (Legitimacy) If so, how?/ If not, why not *Can you give an example?*
2	**What do you see as the enabler/barriers to a national single ethical review/ streamlined process?**	
	2.1	Many people have suggested a single research authority. Would you agree? *Can you give an example?*
	2.2	Is there a link between the NMA and individual hospital governance practices? If so what is the link?
	2.3	Do you think that hospital Boards or senior management consider research as a core hospital activity?
3	**What is the future of the NMA of single ethical review of multi-site trials?**	
	3.1	How strong is the NMA influence on research review processes? (Coercive) *Can you give an example?*
	3.2	Should research offices/hospitals look to others for guidance on research governance? (Mimetic) *Can you give an example?*
	3.3	What credentials or education is required to work in research governance? Should there be standard education? If so what would that look like? Do you think you have a voice or a say in this? (Normative) *Can you give an example?*