2.1. Introduction

The aim of this thesis is to explore the context as well as the formal and informal organisational structures and mechanisms that enable the management of clinical research in AMCs. This chapter is concerned with identifying and applying theoretical frameworks that are appropriate for the development of research questions and the analysis of the study's findings. Chapter one presented three research questions and chapter two provided an example of the context, structures and professional issues related to clinical research management, which corroborate the relevance of those questions. This chapter presents some of the literature within the field of organisational theory, particularly with respect to organisational structure and the management of professionals.

The word "organisation" is derived from the Greek word "organon", which means tool or instrument. Thus, an organisation can be considered a tool that supports the functions required to achieve its goals. As a sociological phenomenon, people tend to pursue goal-oriented activities by establishing or inferring an organisational structure of some description.
Observation suggests that, even in the absence of a premeditated structure, humans employ role differentiation, hierarchical power, authority and control, and create structures to maintain control and maximise the achievement of specific goals (Parsons, 1956, 1960; Pugh, 1990).


For the purposes of this exploratory study it is the latter branch of study that is of particular interest for understanding the relationships between organisations, their environments and their structures.

The first research question presented in chapter one – What is the contemporary context of clinical research in AMCs? – establishes the need to understand the context, or environment that affects AMC structures and their clinical research functions. Within the body of literature on organisation and management, organisational theory, unlike
other theories of management, expressly seeks to consider and integrate the environmental context of organisations with their structures.

The second research question: What are the formal structures and mechanisms that enable clinical research management in AMCs? requires an understanding of formal structure, particularly as it relates to the goals, functions and context of the organisation. Organisational theory is primarily established on studies of the relationships between organisational structure and function.

The third research question: What are the informal structures and mechanisms that enable clinical research management in AMCs? requires an understanding of professional organisations and the structures and mechanisms employed in their management. It is again within the area of organisational theory that one finds the study of professional and health care organisations. Since the impact of professional issues and management may not be apparent within the formal structure of the organisation, then structures and mechanisms related to the integration of professionals in these organisations are characterised in this thesis as 'informal'.

Organisational theory therefore provides a theoretical framework that is relevant to the study of AMCs in relation to their context as well as their formal and informal structures. The following section describes the ways in which organisations are deconstructed and viewed within their contextual environments. The subsequent
sections address the formal and informal structures and mechanisms of organisations and how these concepts apply to the research questions.

2.2. Organisational theory

Mechanic & Dobson (1996) studied seven large US academic medical centres, utilising key informants with diverse perspectives from within each institution. Document analysis and in-depth interviews were undertaken to assess the effect of managed care practices on the availability of research subjects and the impact of reimbursement denials for patients enrolled in clinical studies. The authors found that patients treated in AMCs that employed managed care health systems were less likely to be enrolled in clinical trials than patients in publicly funded AMCs. The primary explanation is that AMCs in the managed care model are sometimes denied reimbursements from insurers if their claimant is enrolled in a clinical study. In the latter case, there would be no denial of reimbursements from Medicare for the mainly subsidised patient population. In another study it was found that AMCs that had lost market share in the contract research subsequently suffered a reduction of other research activities as their research revenue declined (Topping, Hyde, Barker, & Woodrell, 1999). These researchers also found that AMCs that are under pressure to cut costs and generate revenue also have less time available for clinicians to engage in research activities. These demands on researchers to generate the revenue to support their research might explain the increased demand and competition for contracts and
other external funding. As research budgets come under greater organisational scrutiny, applications for funding increasingly incorporate the salary costs of clinical investigators, which have historically been absorbed by the institution hosting the research. A further effect that this competition may have on research funding is that younger and less experienced investigators who lack established track records with funding bodies might be discouraged from applying for funds or conducting research at all.

The data presented suggest that, in order to remain financially viable, many US AMCs have undergone structural transformations mergers and acquisitions, with some establishing managed care health systems designed to contain costs. Indeed, the most significant factors that appear to affect both the formal structures of AMCs and the centralisation of clinical research management are derived from policies and practices designed to contain the cost of health care.

These policies are manifest in the loss of dedicated research time for clinicians and demands for increased accountability in both financial and regulatory affairs. At the same time, the demand for clinical research and competition for commercial clinical trials present new opportunities for research revenue. In response to these factors, many US AMCs have retained the GCRC format and, in some cases, augmented this structure with additional structures for managing financial, regulatory and human resource tasks.
The relationships between the structure, function and environment of complex organisations are not always obvious. Faced with the structural complexity of organisations and the variety of contexts in which they can be examined, organisational theorists often employ metaphors to visualise, understand and convey the meaning of organisation. According to Litterer (1965), the use of paradigms and metaphors is an acceptable technique for the deconstruction and analysis of organisations. He argued the usefulness of metaphors in visualising and describing organisational structures and processes from different perspectives. This is not to say that any or all perspectives and contexts are equally important, or have equal influence, or act unilaterally on the organisation, but that metaphors provide an important vehicle for understanding large, complex organisations operating in complex and dynamic environments (Bolman & Deal, 1997).

Morgan (1997) used metaphors to create a context for describing and classifying organisations. He maintained that organisational theories are based on implicit images, which, if separated out and viewed in a metaphorical framework, allow organisations to be understood in distinctive ways (Morgan, 1997). Examples of metaphors and symbols used by Morgan include machines, organisms, political systems and psychic prisons. Each of these conjures an image of organisations as rigid and inflexible machines, responsive and adaptable organisms, politically motivated or as sources of torment for employees.
For the same conceptual and analytical reasons, Bolman and Deal (1997) demonstrated the usefulness of four paradigmatic frameworks for describing and interpreting meanings and patterns in organisations. These frames, the structural, human resource, political and symbolic are more inclusive than Morgan's metaphors. For example, the structural frame encompasses any organisational form, not just those that are metaphorically mechanistic (i.e. hierarchical and rigid) or organic (i.e. flat and responsive). The human resource frame broadens the scope of the psychic prison and political systems metaphors by viewing organisations in terms of people, their needs and their interactions. The symbolic frame introduces a way of visualising the organisation as a set of symbols, such as the use of academic decorum and traditions by universities and the meanings that the staff and wider community place upon them. While metaphors and frameworks may help us to visualise and describe organisations, their predictive usefulness is unfortunately limited by a tendency to compartmentalise and deconstruct particular organisational characteristics, possibly to the exclusion of overarching, interlocking and dynamic interactions between the compartments. Hence, a reliance on organisational metaphors, while useful for developing analytical frameworks, may limit the context of analysis and hence the generalisability of findings to predict organisational structures.

In order to predict organisational structure it is necessary to acknowledge that the structural choices for organisations, and therefore their functions, may be limited,
or contingent upon, a range of situational factors. In this study these factors include the political, economic, health and regulatory environment as well as the nature and roles of the people involved. The contingency approach to organisational theory is useful for anticipating this dynamic alignment between an organisation's environment and its structure, and helps to balance the notion that there is one best way to structure and manage organisations. This approach holds that an organisation's structural choices are contingent upon its contextual environment, which includes its strategy, tasks, people, history and life-cycle phase (Kimberly & Miles, 1980; Miles & Kimberly, 1980; Quinn & Cameron, 1983). An example of structural contingency is the new business venture, which might be structured in ways that enable it to concentrate its efforts and resources on acquiring capital items and facilities. However, as the business matures restructuring may be necessary to enable the concentration of its effort on economic performance (Quinn & Rohrbaugh, 1983).

The contingency approach to organisational theory considers organisations to be open systems that respond and adapt to complex environmental stimuli. In this way, contingency theory provides scope for the application of organic metaphors and biological analogies. The contingency approach involves viewing firms as individuals within industry populations, subject to laws similar to those that are applied to individuals and populations in a dynamic ecosystem (Hannan & Freeman, 1977; McCaskey, 1974; Tosi, 1976). The main premise of the contingency approach to
organisational theory is that organisations will adopt structures to support the functions required to maximise their goal-achievement in given environmental contexts. Indeed management practitioners are encouraged to employ a contingency approach, by considering the dynamic and interactive aspects of environment, strategy, technology and size as a basis for designing organisational structures (McCaskey, 1974).

However, some contingency theorists are criticised for their tendency to make deterministic assumptions regarding the structural choices for organisations in given environmental contexts (Leavitt & Pondy, 1964). This is exemplified in a study of a manufacturing firm, operating in a stable economic environment, and an electronics firm, operating in an unstable economic environment. That study found that the firm operating in a less stable environment adopted a less rigid and more adaptable organisational structure than the mechanistic structure retained by the manufacturing firm over the same period of time (Burns & Stalker, 1961). The authors identified these findings as evidence that organisations respond to dynamic environments by adopting more flexible, organic structures. The implications of these findings for this thesis are that the dynamic environment of AMCs may predict a migration from rigid hierarchies to more flexible organisational structures.

There are other approaches to understanding organisations besides organisational theory. At the micro-organisational level these include conflict theory, the role of professional power and ethics, and culture clashes at the level of the
individual. Similarly, at the macro-organisational level, other theories abound with respect to communications and strategy. However, as an exploratory study, the focus of interest is tightly held to the contextual and structural aspects as opposed to the behavioural, sociological or strategic aspects of organisations. Organisational theory provides a suitable framework for studying structures while also recognising the importance of an organisation’s environment as well as the impact of professional groups on structure. The following section reviews the literature specifically with respect to the elements and configurations of formal organisational structure.

2.3. Formal organisational structure

Formal organisational structure defines the pattern and flow of power, authority and control among the various roles and positions within an organisation. These structures usually involve hierarchical levels, sub-units, divisions, spans of control, the location of decision-making authority and the channels for information distribution and access. Some of these relationships are formalised while others remain informal. Formal structure is generated through a conscious process, with pathways that are planned and specified through official channels of control and authority, with the intent that organisational members comply. The formal structure is usually represented as an organisational chart with boxes to depict positions, functions and tasks, which are joined by lines that represent the formal conduits of communication and authority. The organisational chart helps identify and legitimise the roles of individuals, groups and
departments within the organisation (Royce, 1988). The formal organisational structure also provides a framework that ensures that communication, co-ordination and integration are effective across departments and enables the organisation to achieve its goals (Thompson, 1967).

The UK’s National Health Service (NHS), which has provided health care to British citizens since 1948, underwent a dramatic restructuring during the period of 'New Right' British politics in the 1970s (Mohan, 1995). These changes were brought about in order to improve effectiveness and efficiency in the country's hospitals and involved the introduction of new governance and structure for its public hospitals. One aim of these changes was to increase the role of doctors in managing clinical resources. However, in a study of UK doctors and managers in NHS hospitals, Bruce and Hill (1995) found that the health reforms had only variable success in achieving this aim, primarily due to increased tensions between management and professionals. In particular, these researchers found hospital doctors to be cynical about their peers performing new roles as clinical directors with additional management accountabilities. These doctors viewed such 'merged' positions as little more than a means to dilute their professional autonomy and to exert greater organisational control over clinical and research activities (Bruce & Hill, 1995). The authors concluded that formal organisational changes alone would be ineffective in bringing about the changes to professional behaviours that were required for the success of the health reforms.
In another study of the post-reforms NHS, 100 managers painted a picture of dehumanisation and administrative chaos in NHS hospitals following the health reforms. Respondents reported how poor managerial decisions were taken because they were the cheaper option (Bower, 1994). While it had been expected that the health reforms would encourage efficiency gains through the application of business principles to the health service, the results of this study suggest that what precipitated instead was a crude and brutal managerialism that was met by significant professional resistance (Bower, 1994; LeGrand, 1999). LeGrand (1999) concluded that the outcomes achieved by the NHS reforms were minimal, partly due to an inadequate understanding of professional and managerial motivations (LeGrand, 1999). The literature would suggest that these findings provide evidence of demarcation and tensions between professional paradigms and managerial paradigms in the hospital setting.

Meyer and Rowan (1997) have suggested that an organisation's formal structure is also an important symbol for both organisational members and external parties, who may appraise an organisation on its adherence to structural norms. This is particularly relevant when the organisation seeks legitimacy for its traditions and practices. As described in chapter two, the University of Toronto and the Hospital for Sick Children established a research institute as a symbol of assurance with respect to capability and competency as an investigative site for clinical research. Indeed, some AMCs, such as the Harvard Medical School and Massachusetts General Hospital, exist in a context rich
in history and tradition. As such, their structural configurations may serve as symbols to convey a sense of conformity with norms and stability of operations and thus confer legitimacy in the eyes of public and private stakeholders.

Several studies have empirically demonstrated that formalisation, specialisation and centralisation (Blackburn, 1982; Child, 1974; Fredrickson, 1986; Sathe, 1978), and integration (Galbraith, 1973; Lawrence & Lorsch, 1967; Mintzberg, 1979) are among the most consistent dimensions of an organisation's structure (Champion, 1975; Fredrickson, 1986; Hall, 1977; Van de Van, 1976). Pugh et al (1968) described five basic elements of organisational structure: (1) specialisation, (2) standardisation, (3) formalisation, (4) centralisation and (5) configuration. Structural specialisation, or the division of labour, is characterised by organisational branches or sub-units, each representing a parameter by which official duties are distributed. Standardisation is the process of defining important and regular events and applying formal procedures for the various functions. Standardisation is an important feature for regulating activities and standardising outputs in professional bureaucracies. Formalization is the extent to which rules, policies, procedures and communications are documented. Mintzberg (1979) described professional organisations in terms of the degree of formalisation required to guide member behaviour and reduce output variability. Since formalisation is instilled and enforced through member training, formalisation and training are mutually reinforcing, if not substitute, activities. An unfortunate aspect of formalisation
is that decisions tend to become enshrined, and hence less reversible. Thus, formalisation may limit the acceptance of new ideas (Kimberly & Miles, 1980) and create more administrative work, while the decentralisation and the specialisation of labour contribute to the sheer complexity of the professional organisation (Dunkerley, 1972).

Centralisation is the degree to which key decision-making authority is distributed in the organisation. Authority to make decisions can be ascertained by identifying the last person whose assent must be obtained before legitimate action is taken. The fifth element, configuration, is the representation of formal structure, as represented by the organisational chart. Depending on the degree of specialisation, standardisation and formalisation required in order to maintain the required level of control and co-ordination, an organisation's configuration may be steep and hierarchical or flatter, with more distributed control. The configuration is comprised of boxes and lines to depict, and hence legitimise the roles, positions, lines of authority and spans of organisational control. Sadler (1991) has suggested three fundamental organisational needs that need to be considered when designing an organisation's structure: control, co-ordination and integration. Organisational control is exercised directly or indirectly and to the degree required to maintain an alignment between organisational members and organisational goals (Child, 1972; Galbraith, 1977; Tosi, 1976). When tasks can be clearly specified and outputs can be precisely measured, direct control is appropriate. Also, when the tasks or
activities are hazardous, such as surgical procedures, the use of close or tight control mechanisms is more likely (Morgan, 1997; Sadler, 1991). In this case, control might be exercised through the extensive use of formalisation and standardisation of procedures. Control is often construed as a negative aspect of organisational life. However, rather than characterise organisations with high degrees of centralised control as 'bad', and those allowing more individual discretion and autonomy as 'good', it may be more useful to consider the appropriateness of different control systems in relation to different situations (Sadler, 1991). For example, with work involving high degrees of artistic, creative or innovative activities, such as research, or where the nature of work requires rapid and flexible responses, direct control mechanisms may be inappropriate.

The continuum of organisational configurations ranges from rigid and steep hierarchical bureaucracies to flatter and more flexible, organic structures (Pugh, Hickson, Hinings, & Turner, 1968). The following paragraphs describe six of the more common clusters of organisational configurations along this continuum in relations to the other four elements of structure. The 'mechanistic' or centralised functional form of organisational structure is characterised by systems that espouse rules, regulations and procedures (Lucas, 1997). This bureaucratisation is common in organisations where roles, procedures and tasks are precisely defined and when work processes are discreet, predictable and critical to success (Weber, 1947). These steep and hierarchical configurations gained widespread application in American organisations during the
1920s, particularly within industries that adopted the mechanistic management theories of Frederick Taylor (Mitchell, 1982). Decision-making, control, authority and communications in centralised bureaucracies are focused toward the top of a pyramidal structure (Ostroff, 1993).

Although activities such as marketing, manufacturing and R&D may be grouped separately, control is centralised at the apex of the organisational hierarchy. However, these bureaucracies have been found to be relatively unresponsive and to fare poorly in rapidly changing external environments (Mitchell, 1982). As the size and complexity of these organisations increase, their ability to respond to environmental change tends to decrease (Wieland & Ullrich, 1976). It has been suggested that this loss of responsiveness may be due to the organisation's reliance on highly centralised control when the complexity and divisionalisation of the structure actually requires more decentralised control mechanisms (Carlisle, 1969; Ostroff, 1993).

'Steep' structures, such as those of a centralised mechanistic bureaucracy, have been found to be more appropriate for organisations operating in stable environments and when the work processes are clearly defined (Gerwin, 1981). However, mechanistic divisions create compartmentalisation between different hierarchical levels, different functions, different roles, or different geographical locations. The resultant inter-organisational boundaries and segmentalism can discourage organisational fluidity, a condition identified by Sapienza (1995) as particularly vital for innovation.
Therefore, if an organisation is structured in a manner that accommodates fluidity through increased horizontal linkages, it will be better positioned to accept ambiguity, collaboration, intellectual challenge and transparent communication than a more rigidly structured organisation (Kanter, 1985; Sapienza, 1995).

A high degree of standardisation is another feature of the mechanistic organisational structures. While reducing uncertainty, particularly with respect to the outputs of specialised, professional activities, it has been suggested that increased standardisation slows organisational responsiveness to changing environments, and hence limits its strategic choices (McCaskey, 1974; Meyer, 1977; Miner, 1982; Ouchi, 1974). Mechanistic organisations also tend to advance their goals by promoting standardised and risk-averse behaviours, which may be responsible for creating the perception of these organisations as boring and stifling in terms of innovation (Burns & Stalker, 1961; Dougherty & Hardy, 1996; Robertson & Langlois, 1995). This has significant implications for organisational hierarchies such as AMCs, which require a high degree of standardisation with respect to their professional activities, but which also require sufficient flexibility to enable it to adapt to changes and encourage the creativity and innovation needed for research.

Following World War II, some large organisations were faced with the increased complexity of expanding product lines and functions, which needed to be controlled, co-ordinated and integrated (Morgan, 1997). Organisational growth and ageing encouraged
the growth of market-based units, or divisions, which became superimposed on the traditional centralised bureaucracy.

Du Pont and General Motors are examples of organisations that altered their structures from centralised bureaucracies to decentralised, divisional forms. One rationale for this change was that decentralisation through a divisional structure would reduce the workload of top management and allow executives to concentrate on the strategic, rather than operational, aspects of decision-making (Mintzberg, 1973). However, instead of having one 'complete' structure, divisions tend to develop their own structural hierarchies and identities (Wieland & Ullrich, 1976). As a result, these organisations have been observed to experience difficulties when applying co-ordinating and integrating mechanisms across disparate divisions and subunits (Scott, 1973). Other researchers have also demonstrated that the intense efforts required to co-ordinate the functions and divisions of these organisations eventually diminish the flexibility that is anticipated through decentralisation (Miles & Snow, 1992).

Thus, both the centralised functional and decentralised divisional forms employ pyramidal hierarchies of different breadth. Both forms support a high degree of specialisation, standardisation and formalisation, and can be described as mechanistic, as opposed to organic. However, as organisations move from a centralised functional form to a decentralised divisional form, the decentralisation of control and authority increases the need for co-ordination and integration between those divisions.
Organic structures are less rigid and hierarchical than mechanistic hierarchies. It is this relative flexibility that enables the organically structured organisation to better anticipate and respond more quickly to threats and opportunities emerging in their operating environment (McCasky, 1974; Morgan, 1989; Tosi, 1976). Mintzberg (1979) defined organic organisations as those that operate in the absence of standardisation. Organic structures have been demonstrated to be effective when there is uncertainty in the task environment, when the tasks are not well enough understood to be 'programmed', or when organisational members thrive on ambiguity, variety and problem-solving (Osborn & Hunt, 1976). Lawrence and Lorsch (1967) described this organic organisational form as highly decentralised and differentiated, while other authors describe these structures as intensely integrated (Galbraith & Edstrom, 1976; Thompson, 1967).

Indeed, organic structures tend to have flatter configurations and require extensive integrative mechanisms in order to maintain control while maximising responsiveness and flexibility. An example of an organic configuration is the adaptive organisational structure. Some industries, particularly those that utilise project management practices and that require a high degree of strategic and structural responsiveness, have an adaptive organisational structure (Ansoff & Brandenburg, 1971; Wieland & Ullrich, 1976). The Manhattan Project, an endeavour that required a large, complex and multidisciplinary work force for the purpose of developing and producing
the first atomic bomb, is an example of an adaptive organisation. Deemed an organisational success, the US Department of Defence subsequently required their contractors to adopt a similar organisational structures (Carlisle, 1969). Adaptive structures utilise decentralised control mechanisms, which can provide flexibility within project units that are charged with specific objectives. Adaptive organisations utilise a high level of standardisation in order to maintain organisational control. Project teams can be created and disbanded in response to identified problems and opportunities, hence enabling strategic responsiveness (Ansoff & Brandenburg, 1971). However, the higher level of decentralisation within adaptive structures also increases the need for robust integrative mechanisms to support co-ordination between project teams and the administrative hierarchy.

A variation on the adaptive structure is the matrix organisation. Matrix organisations, which emerged during the 1960s and 1970s, combine elements of both the centralised functional and the decentralised divisional forms. However, the matrix organisation typically arranges personnel by function, while simultaneously grouped as project units. Matrix structures have been applied to both relatively stable organisations, such as city administrations, and to dynamic organisations, where project work relies on flexible interdependencies. Although shown to be effective for developing new activities and for co-ordinating complex interdependencies, the matrix structure sacrifices a primary organisational control principle: the unity of command. Is
has been suggested that this affects superior-subordinate relations, where individuals may be responsible to more than one 'superior', or simultaneously belong to more than one project group (Wieland, 1976). Although matrix organisations enable flexibility in the face of environmental turbulence and uncertainty, they can also be disadvantaged by the high cost of administration and the difficulty in establishing communications between sub-units (Charns et al. 1981).

Indeed, Charns described AMCs as prime examples of matrix organisations, with large numbers of faculties, departments and various specialised activities. As discussed in chapter one, AMCs are also notable for the relatively high cost associated with their administrative overheads, created both through an extensive bureaucracy as well as the costs of their teaching and research missions. However, some authors have suggested that the divisional form best describes the groupings of medical specialties within a hospital (Leatt, Shortell, & Kimberly, 1997). These observations of AMC structures will be discussed further at the end of this section.

In the 1960s, Bennis & Slater (1964) and Alvin Toffler (1970) signalled the emergence of highly decentralised organic organisational structures, called adhocracies. These organisations have little formalisation or standardisation, relying instead on horizontal specialisation. Adhocracies are based primarily around activities that require formal or specialist training and are organised as small interdisciplinary project-specific teams on an ad hoc basis. A good example of a functioning adhocracy is the Manned
Space Flight Center of the National Aeronautics and Space Administration (NASA). In response to changing project needs, this centre changed its structure seventeen times in its first eight years (Litzinger, Mayrinac, & Wagle, 1970). Decision-making in an adhocracy is widely distributed and extensive use is made of informal structures such as integrative devices and liaison mechanisms to maintain control and co-ordination. However, adhocracies tend to act inefficiently in carrying out 'ordinary' functions, since they are really designed to efficiently carry out ex/ra-ordinary functions. One explanation for this inefficiency-efficiency paradox may be the high cost of communication and decision-making in a distributed structure, especially in the early stages of a project. The ad hoc nature of project teams suggests that adhocracies are examples of highly adaptable structures: that is, project teams exist as long as they support the needs of the organisations, but disappear when either the environment or organisational needs no longer require them. Mintzberg (1979) described adhocracies as highly competitive and, at times, ruthless organisations.

"Network organisations" (Miles & Snow, 1986) and "organising networks" (Uzzi, 1996, 1997) describe organisations that co-ordinate their activities only through organic or informal networks (Gerlach & Lincoln, 1992; Nohria & Eccles, 1992). A key characteristic of the network organisation structure is the use of informal social systems rather than formal bureaucratic structures to co-ordinate complex products or services while operating in uncertain and competitive environments (Piore, 1984; Ring, 1992;
Snow, 1992; Jones, 1997). Control and authority mechanisms are very loose in a network organisation, suggesting that co-ordination, as opposed to control, is the unifying principle of these organisations. The implication for professional organisations, such as AMCs, is that common goals might be achieved in the absence of any formal organisational structure.

These six examples of organisational structure: centralised functional form, decentralised divisional form, adaptive organisations, matrix organisations, adhocracies and network organisations describe a continuum of organisations from those requiring tight and centralised control to those based on only social or ideological control. Organisations that have control-oriented value systems tend to consolidate control by centralising decision-making processes and decreasing employee or departmental discretion and flexibility (Burns & Stalker, 1961). The structures these organisations adopt tend to be highly mechanistic, with an emphasis on formal, standardised procedures and centralised control mechanisms. In contrast, organisations that are flexibility-oriented tend to decentralise and distribute their decision-making and co-ordination across flatter, more divisionalised structures, in order to be more responsive to environmental change. It is not surprising therefore to find that organisations operating in turbulent and fast-moving business environments and industries tend to migrate toward more organic structures (Child, 1981; Osborn & Hunt, 1976; Sims & Gioia, 1986). As organisational structures become 'flatter', there is an increased reliance
on indirect control through horizontal communication and informal mechanisms.

However, these flatter, more widely distributed organisational structures also create confusion, ambiguity and tensions between their members as a result of poor communications and competition for resources. It has been suggested that this politicisation may be due to inadequate horizontal communications and liaison mechanisms (Shore, 1995).

Academic medical centres are complex professional bureaucracies. Their organisational structures have been described as both mechanistic decentralised divisional forms by Leavitt et al (1997) and as more organically structured matrix organisations by Charns (1981). These descriptions and observation suggest that AMCs are comprised of multiple divisions or departments, with some degree of authority and control distributed to the various units. The literature presented in this section also suggests that in professional bureaucracies, the levels of specialisation, formalisation and standardisation tend to be high in order to reduce variability in the divisional outputs. In this manner, the administrative hierarchy exerts some control over professional activities in these structures.

In chapter one, the environment of AMCs was described as undergoing rapid change during that time period, which appears to be contrary to predictions made by some theorists that organisations in dynamic environments will migrate toward more flexible, organic structures in order to maximise their responsiveness (Burns & Stalker,
1961). What appears to have happened to AMCs in the US is that they have responded
to an unstable environment by becoming even more divisionalised and complex through
restructuring, mergers and acquisitions. The implications for clinical research
management is that these activities are likely to be structured as specialised divisional
functions, with organisational control exerted primarily through formalisation,
standardisation, and specialisation, exemplified by the matrix organisation. This context
suggests that the co-ordination and integration of activities might be a primary control
mechanism in AMCs.

As well as matrix-like divisionalisation, AMCs are usually comprised of several co-
operating organisations, usually a university and a hospital. The administrative
bureaucracies of these organisations are pyramidal configurations with the locus of
control and authority resides at the apex, with control and authority distributed down
to the various divisions. Embedded within the formal organisational structure of AMCs
are the professional bureaucracies, which give legitimacy to the organisations'
specialised functions. As will be described in the following section, these professional
structures are rarely articulated within the formal organisational chart.

**Figure 2.1**

*Control and Authority in the Professional Bureaucracy*
Within the administrative hierarchy, authority and control flow from the top down, while in the professional hierarchy authority is derived from its constituent base and flows from the bottom up (Freddi & Bjorkman, 1989; Mintzberg, 1998). Professional associations are structured such that authority and control stem from a member base and flow upward to elected or professionally appointed representatives. Thus, while the administrative bureaucracy exerts hierarchical control over organisational members through standardisation and formalisation, professionals exert collective control over the administrative bureaucracy. In AMCs this complex interaction between the formal administrative structure and the informal professional structure is compounded by the multiplicity of organisations and professional groups involved. These parallel hierarchies are common in academic medical centres, where academic and clinical professional bureaucracies run parallel to the administrative structures of the university and the hospital. A typical AMC might consist of a university, one or more hospitals and a host of professional groups, such as academics, doctors, nurses and technologists. The literature suggests that highly divisionalised and decentralised organisations such as this experience increased ambiguity and tension as various departments and divisions vie for resources. Given the multiple, parallel formal and informal structures of AMCs, the literature predicts that a robust system of horizontal communications is needed to co-
ordinate and control activities and mitigate tensions within and between departments. Figure 2.1 illustrates the parallel administrative and professional structures of a simple AMC.

This section has presented literature that describes formal organisational structure as a product of rational planning and represents an explicit interpretation of the organisation's purpose and functions. However, the formal structures of AMCs, as professional bureaucracies, may not reflect how people actually relate and interact within the organisation. It has been suggested that organisational structure is a product not only of planning and design, but also goal congruence between organisational members (Lawler, 1993; Nystrom, 1981). In other words, invisible and emotional structures that are collectively shared by organisational participants, such as beliefs, history, attitudes, values and assumptions create and maintain the 'actual' structure of the organisation (Banner, 1995). This observation is corroborated by the Toronto example in chapter two, which described the different research practices that were accepted by different departments and how these practices varied from the expectations of the administrative bureaucracy. Indeed, the functional isolation of sub-units within the administrative and professional bureaucracies of the AMC may have been one of the factors leading to the failures in management of the LI clinical trials at the Hospital for Sick Children. The following section presents studies from the
organisational literature, which discuss the management of professionals and the implications of professional management on organisational structure.

2.4. Informal organisational structures

Organisations that adopt more organic or fluid structures demonstrate an increased reliance on indirect control through integrative and liaison mechanisms relative to steeply hierarchical and mechanistic organisations (McCaskey, 1974; Morgan, 1989; Tosi, 1976). This implies that there might be a greater reliance on informal structures than is evident from the analysis of formal organisational charts, particularly when a high degree of co-ordination and integration is needed to perform complex tasks. Indeed, as professional expertise becomes increasingly critical in decision-making, the distinction between formal authority and informal authority may become blurred. These situations may require the explicit acceptance of organisational members to the use of informal liaison devices to resolve tensions between the management and the clinical decision-making loci.

The introductory chapters of this thesis described and illustrated the influence that professional activities and behaviours have on clinical research management. The reviewers of the L1 clinical trials suggested that differences between professional norms and organisational management in academic medical centres create tensions might be mitigated through the use of informal organisational structures. It was therefore
recommended that the organisations implement informal liaison mechanisms in order to enhance communications across organisational and professional boundaries.

This suggests that infrastructure, such as formal structure, policies and systems, as well as informal structures, such as liaison mechanisms, are important in managing clinical research.

Studies within the body of organisational theory literature describe and discuss the unique impact that professionalism has on organisational structure. This section expands on the descriptions of formal organisational structures in section 2.2 and offers insights into the informal structures and mechanisms required for managing professional bureaucracies in the context of the final research question: What are the informal structures and mechanisms that enable clinical research management in AMCs?

Professional organisations are structured around the work of highly trained individuals who understand what they need to do and perform their tasks independently from the formal management structure of the organisation (Litwak 1961; Bucher and Stelling 1969; Freidson 1984). Professionals are controlled directly through the use of internal training, rules and procedures, or to control it indirectly through the processes of professional recruitment (Freddie & Bjorkman, 1989; Mintzberg, 1998). As in other professions, these groups have developed elaborate training mechanisms,
sophisticated and specialised vocabularies, intricate prestige hierarchies and specialised procedures for validating and communicating their work. Characteristics of professional bureaucracies include formal training and indoctrination processes particular to each profession. Indeed, professional organisations such as hospitals, universities and accountancy firms often rely on outside institutions to train, certify, set standards and guide practitioners in their professional roles (Argyris & Schon, 1974).

Initial training typically takes place over years in a university or special institution, where the skills and knowledge of the profession are formally programmed into the would-be professional. During an internship period, formal knowledge is applied and skills perfected under the close supervision of professional members and augmented by continual professional training and accreditation.

Professional associations typically examine trainees to determine whether they have the requisite knowledge, skills and norms to enter the profession. These standards often originate outside of the organisation's structure, where professionals maintain functional authority and control through their expert power. All of these practices can insulate and protect professionals from outside influence, authority and control, particularly that of the formal organisational structure (Argyris & Schon, 1974; Bower, 1994; Brett, 1996; Charns, Lawrence, & Weisbord, 1981; Hall, 1981).
In professional organisations, the informal expert power system is superimposed on the formal system of administrative authority (Bower, 1994). Where decisions are highly technical or esoteric, and where these decisions are critical to the organisation, experts within the professional organisations tend to wield considerable power, whether formally acknowledged or not. As expertise becomes increasingly important in decision-making, the distinction between formal authority and informal authority may become blurred, which may pave the way for an intrinsic acceptance of informal structures and mechanisms employed to resolve tensions between decision-making loci (Mintzberg, 1979). While most professional work consists of applying standard routines, a significant amount requires co-ordination and integration with other professional groups, such as doctors, nurses or technologists as well as administrators and managers. Not only do professionals control their own work, but they also seek collective control of the administrative decisions that affect them. In these circumstances structural liaison devices, such as committees and task forces, are especially important to achieve co-ordination and integration.

In hospitals and universities, clinical and academic professionals do the primary work of the organisation while the function of hospital and university administrators is to support and assist the professionals by providing formal structures, facilities, resources and personnel (Wieland & Ullrich, 1976). Perrow has described the divisions
and layers of professional structures within the administrative bureaucracy of a hospital in this way:

"The medical personnel in hospitals are generally highly organized in a structure that parallels that of the administrative staff of the hospital. The medical staff has its own nursing committee, outpatient department committee, pharmacy committee, and so forth, and in between the major ranks of junior and senior attending staff are several clear distinctions in grade, with appropriate powers and entrance criteria." (Perrow, 1986:28) For professionals, authority and control are derived from professional structures, associations and norms. Professionals demand freedom and autonomy to exercise their clinical decisions, a position that can be contrary to an administrative hierarchy demanding standardisation and formalisation to maintain control. Professional academics also demand recognition of their core values of free inquiry and the disinterested pursuit of knowledge, which also creates organisational tensions with the administrative hierarchy. Peter Boland, a health care consultant in Berkeley, California, refers to these multiple hierarchical structures as the chief organisational weakness of academic medical centres (Hagland, 1996). Thus, paradigmatic differences between members of the professional and administrative hierarchies present an additional challenge to the integration, co-ordination and control of organisational activities such as clinical research management.
As illustrated in Figure 2.1, power and authority in academic medical centres are delineated within parallel hierarchies, one democratically-based and bottom-up for professionals and the other a top-down hierarchy for the administrative support staff. The literature suggests that there may be conflicting goals between the parallel administrative and professional bureaucracies of the hospital and the university (Georgopoulos, 1974). Moreover, the existence of both an administrative and professional hierarchies might cause the lines of authority in professional organisations to become obscured. This might explain why professional norms and behaviours tend to become accepted in spite of being incongruent with organisational expectations.

As described above, the difference between professional norms, goals and behaviours and those of the administrative bureaucracy have been associated with fundamental differences in their different organisational paradigms. In applying an integrative framework to the study of hospitals, Glouberman and Mintzberg (2001) found four distinct paradigms, or organisational realities, amongst their staff. Each of these 'four worlds' is based upon the distinctive attitudes, value sets and missions of four groups of staff. The medical and nursing staff were both focused on care missions, although each of these professional groups maintains their own separate hierarchies of professional authority and control. The dominant paradigm for managerial staff was control. A fourth paradigm, called community, was represented by those involved in social governance activities, such as hospital social workers and community liaison
teams. The authors suggest that these paradigms can reinforce the attitudes of staff and create divisions as each group seeks to advance its particular mission within the hospital (Glouberman & Mintzberg, 2001). This difference between the paradigm of medical staff and managerial staff also extends to the recognition of control and authority. Charns et al (1981) studied the pattern of authority in academic medical centres and reported that 41 percent of physicians surveyed claimed they were responsible to no one. This finding supports other studies that identify differences between the professional orientation toward service and the bureaucratic orientation toward procedural compliance as a common source of conflict in professional organisations (Blau, 1967; Bower, 1994; Bruce & Hill, 1995; Cullen, Anderson, & Baker, 1986).

The management of scientists and researchers is recognised for its particular difficulties and unique challenges (Thatcher, 1980). Research management requires an understanding of both business as well as research processes and professional norms. One of the challenges for clinical research management is the tendency for doctors and other health professionals to hold allegiance to their professional norms above those of other organisations (Degeling, Sage, Perkins, Kennedy, & Zhang, 1999; Inglis, 1999). This behaviour was evident in the Toronto case, where professionals followed the norms, behaviours and practices of their colleagues with little deference to the administrative requirements of the organisations involved. Peer accountability matters as much to professionals as any 'objective' performance measures of organisational goals (Kreiner &
Schultz, 1993; Sapienza, 1995). As professionals, scientists and health care providers jealously guard their autonomy (Pettus, 1996). The goal of scientists, including clinical researchers, is to advance knowledge, with the autonomy to choose the problems to be addressed and the methods for their investigation (Tosi, 1976). In contrast, managers often receive much of their training on the job within organisations and tend to be more accepting of hierarchical direction and control than researchers and other professionals (Walsh, 1995; Whyte, 1957). While managers are embedded in the formal administrative structure, health professionals defer principally to their own professional hierarchies.

Thus, managers are faced with controlling is a patchwork of enclaves and fiefdoms, many in competition and most acting as autonomously as possible. This suggests why an organisation such as the HSC or the University of Toronto might have robust policies, structures and mechanisms for managing clinical research yet fail to be effective in achieving its aims without the co-operation of the professional groups that perform these tasks. In the Toronto example, it appears that the policies and directives originating from the administrative hierarchy with respect to research were largely ignored by the professional constituency, and substituted with practices acceptable to professional and departmental norms.

The skill sets for researchers and managers are different, which may account for a common observation that good scientists do not necessarily make good managers
However, managers do need a sound understanding of the technical and scientific aspects of research. Studies have shown that managers of successful research units tend to be scientists, with an outlook and many of the values of subordinates, but also trained and skilled in business matters (Freddi & Bjorkman, 1989; Litterer, 1970; Shore, 1995). In these situations, the research manager functions as the principal link between the scientists and the administrative hierarchy, serving to translate scientific information into terms other managers can understand (Tosi, 1976). In other words, research managers tend to adopt intermediary positions between the administrative and professional bureaucracies.

For multi-site organisations, which are common among academic medical centres, geographical differences can create further boundaries and distinctions between staff and departments. Particularly in the case of mergers and acquisitions, the perceived organisational boundaries may linger as members cling to the 'way things used to be done' (Jarillo, 1993). Whether real or perceived, these boundaries tend to translate as "barriers" in terms of intra-organisational integration. Thus, another challenge for managing clinical research in AMCs is to co-ordinate professionals and activities across multiple intraorganisational boundaries.

As described in section 3.2, complex professional bureaucracies tend to rely in informal structures, such as liaison or integrative devices, to minimise the effect of intra-organisational barriers and to coordinate tasks. One of the aims of liaison devices is to
assist in aligning sub-unit goals with overall organisational goals in order to maximise effectiveness (Negandhi & Reimann, 1973). Early studies of liaison devices have revealed an expectation that personnel who perform liaison roles will move easily across professional and functional boundaries, acting as intermediaries to facilitate the flow of communication between people getting on with their jobs. When such units work successfully, they have two characteristics: (1) a structure that is intermediary to those of the linked sub-units; and (2) personnel whose outlooks and values are intermediary to those of the sub-unit members. The literature suggests that the intermediary position and value orientation of those in liaison roles will improve the effectiveness of the liaison function (Mintzberg, 1979; Tosi, 1976). These findings may explain observations by Mintzberg (1979) that hospital and university managers who do not have both business and management skills as well as a sound knowledge of the professional work involved may not be suitable for these positions.

As discussed in section 2.2, the greater the number of organisational divisions, the greater the need and challenge to co-ordinate and create effective linkages between the tasks. Co-ordination is particularly important when there is a high degree of task interdependence (Banner & Gagne, 1995; Daft, 1989; Galbraith, 1973; Kilmann, Pondy, & Slevin, 1976a). Co-ordination can be achieved voluntarily, where individuals or groups identify their mutual needs and apply the appropriate mechanisms. Examples of liaison devices and informal mechanisms used to co-ordinate professionals include line
management, staff specialists, co-ordinators, facilitators and project groups. The degree of co-ordination achieved has been linked to how individual members identify with the organisation, how they perceive their role in the organisation, and how organisational practices promote and enable voluntary co-ordination (Vizjak, 1994). In contrast to voluntary co-operation is the directed method of co-ordination, such as a standing committee, where individuals are told what to co-ordinate, with whom and where (Litterer, 1965).

As opposed to formal organisational structures, informal structures are described as non-linear and multi-directional (Jarillo, 1993), in constant flux (Galbraith & Edstrom, 1976) and are usually intertwined and indistinguishable from the formal organisational structure (Hall, 1981). The pathways of the informal structure are implicit, unspecified, unwritten and unplanned, sometimes arising out of, or in reaction to, the formal organisational structure (Etzioni, 1986). This has profound implications on how organisations that perform complex tasks, like hospitals and universities, organise and manage their activities. Indeed, there may be a far greater reliance on informal structures than on formal structures in order for these organisations to achieve the degree of co-ordination, integration and required.

A common liaison device for integrating and co-ordinating inter- and intra- organisational activities is the 'task force' or temporary committee (Hall, 1981; Tosi, 1976). These devices do not involve a large commitment of organisational resources and
are not permanent structural devices. Instead, they provide a formally legitimised mechanism by which members of various sub-units can co-ordinate their efforts. While the internal processes of task forces and committees often reflect characteristics of an informal structure, they may also receive formal endorsement from the organisation vis-à-vis inclusion in formal organisational charts and company policies. Although committees are often held as a solution to many organisational problems, they can also be the cause of others, and are probably the least effective means of achieving co-ordination between different groups (Tosi, 1976). The effectiveness of committees depends on the abilities of the chairperson and committees may be uneconomic in terms of staff time to output ratio. Moreover, the logistics of committee meetings can slow the decision-making process and further impede effectiveness. Delays such as these are especially untenable in commercial clinical research, where organisational responsiveness is paramount.

Liaison devices or integrative mechanisms can also be in the form of individuals, particularly those who work between groups with disparate paradigmatic views within the organisation. In this case, meetings provide a common vehicle for mutual adjustment and for facilitating internal communication.

Task forces and standing committees are other examples of informal structural mechanisms that serve this function. These are commonly used when the work is horizontally specialised, complex and highly interdependent, and when close co-
ordination and mutual adjustment are most required (Mintzberg, 1979). Liaison devices, such as committees and task forces, are used extensively to achieve the co-ordination and control of complex and specialised tasks, which may fall outside the ambit of the formal organisational structure (Miller, 1988).

2.5. **Summary**

This chapter has described the literature on organisational theory in order to develop a theoretical framework for approaching the three research questions. This section summarises the literature with respect to each question and the implications for the methodologies to be employed.

The first research question asks: What is the contemporary context of clinical research in AMCs?

Organisational theory recognises the impact of operating environments, or context, on how organisations organise and manage their activities. As discussed in chapter one, the operating environment for many AMCs has been in a state of flux, primarily due to economic pressures, over the past twenty years. Moreover, the clinical research environment is also dynamic, particularly in terms of advances in biotechnology and regulatory practice. The contingency approach to organisational theory predicts that environment will impact on the structural configurations that organisations adopt. As described in the last section, some contingency theorists predict
that organisations will adopt structures that will maximise goal achievement with respect to the operating environment. The implication for AMCs is an expectation that these organisations may 'migrate' from rigid hierarchies to flatter more organic structures in uncertain or unstable environments (Burns and Stalker, 1961). By studying the structures of AMCs in the current environment, this study will contribute to an understanding of the generalisability of these predictions.

Organisational theory also provides metaphors and paradigmatic frames for conceptualising and analysing organisations. Metaphors are used in this thesis to describe the degree of centralisation and control used by organisations as ranging from machines to organisms. The paradigmatic frameworks of Bolman and Deal (1997) also provide distinctive contexts in which organisations can be studied and analysed. While this thesis principally applies a structural approach to the analysis of AMCs, the human resource approach is also relevant for understanding the impact that professional behaviours have on formal structure. Although not used in this study, the symbolic paradigm might view AMC structures as symbolic of relative conformity, stability, competency and capability, while the political frame might view AMCs as collections of competing ideological interests.

The second research question asks: What are the formal structures and mechanisms that enable clinical research management in AMCs?
The study of formal organisational structure is central to organisational theory. The literature related to organisational structure provides an understanding of the basic elements of formal structure and how these elements are combined to meet organisational needs, such as control. The required levels of specialisation, standardisation, formalisation and centralisation result in a continuum of organisational configurations, which tend to cluster into common types. Utilising metaphorical analogies, these clusters range from the mechanistic to the organic. The mechanistic, steeper configurations are represented by the centralised functional and the decentralised divisional forms, and allow for tight organisational control. Both types exhibit high levels of standardisation and formalisation, although the decentralised divisional form allows for a higher degree of specialisation. The organic, flatter configurations are represented by the adaptive, matrix, adhocracy and network organisations. These structures are characterised by increased levels of specialisation, decreased centralisation, looser organisational control and environmental conditions. However, as centralisation decreases, the need for co-ordination and integration tends to increase. In the case of the adaptive and matrix organisations, a primary co-ordinating mechanism is to increase standardisation and formalisation. In the case of the more extreme network organisations, the need for direct control is non-existent, and hence these organisations require only a minimal amount of standardisation and formalisation.
Organisations adopt structural configurations that reflect their need for control and co-ordination through various degrees of centralisation, standardisation, formalisation and specialisation required. The simplest organisations employ direct supervision as the primary mechanism for co-ordination.

Co-ordination is achieved by having one person take responsibility for the work of others, issuing instructions to them and monitoring their actions. As organisations formalise their behaviours and develop horizontal and vertical specialisation, co-ordination is primarily achieved by the standardisation of work processes. The divisional, or matrix structure, as described in section 3.2, presents a greater challenge to co-ordination due to the decentralisation of control and authority. Since it is more difficult to employ direct supervision or to monitor skills and work processes across a divisionalised organisation, the standardisation of outputs is a primary co-ordinating mechanism. The structural adhocracy, however, is highly decentralised in its design in order to accommodate a range of horizontal specialisations. Since control and authority is distributed throughout the organisation, the primary co-ordinating mechanism is mutual adjustment. Figure 3.2 presents this continuum of organisational configurations from the rigid machine bureaucracy to the flexible, organic structures of the network organisation.
The organisational structures presented in Figure 2.2 provide a context for understanding the formal structure of AMCs, which are highly specialised professional
bureaucracies, which rely on standardisation and formalisation to maintain organisational control. The hospitals and universities that comprise AMCs have been described in the literature as either matrix or adaptive organisations. Figure 2.2 distinguishes these two structures by the way they make use of 'project teams', which can be established and disbanded in response to the organisations needs. The observations presented thus far suggest that the matrix is a more accurate description of the formal structure of academic medical centres, which appear to have relatively stable departmental structures. However, as discussed in section 2.2, AMCs have the additional complexity of multiple hierarchies, which has the effect of increasing the horizontal spread of the overall organisation. These parallel hierarchies may therefore generate an increased reliance on informal organisational structures.

These are discussed below in terms of the third research question: What are the informal structures and mechanisms that enable clinical research management in AMCs?

Informal organisational structures, such as liaison roles, committees and task forces, arise largely in response to the co-ordination and integration requirements of the organisation. These requirements may change as a result of changes to the organisation's environment or formal structure. As described in section 2.3, these integrative mechanisms are especially important for organisations with flatter, more organic formal structures. Moreover, the literature suggests that the highly specialised,
professional bureaucracies in particular require a significant degree of liaison in order to facilitate communications between the management in the administrative hierarchy and professionals.

The multiple organisational hierarchies and specialisation of the AMC introduces integrative challenges, particularly given the paradigmatic differences between managerial and professional hierarchies, a dichotomy that is a common source of conflict and tension in professional organisations in general. The challenge for managing professionals and researchers is to communicate and co-ordinate activities across multiple departmental, professional, administrative and organisational hierarchies. In the professional bureaucracy, training, specialisation and decentralisation are important design components. These organisations rely on the standardisation of skills as the primary co-ordinating mechanism. As described earlier in this chapter, as organisational structures become more decentralised, a greater reliance is placed on informal structural mechanisms. In these cases, mutual adjustment a mechanism employed not only co-ordinate but also to mitigate tensions between the administrative and professional hierarchies. Mutual adjustment has been described as a co-ordinating mechanism used by organisations to minimise intra-organisational barriers to facilitate the integration and coordination of tasks (Mintzberg, 1979). Mutual adjustment, which is associated with the informal organisational structure and serves as a primary co-ordinating mechanism when there is a high reliance on liaison for control (Mintzberg,
It is therefore reasonable to expect that mutual adjustment might also be an important co-ordinating mechanism for managing clinical research in academic medical centres.

The research questions posed in chapter one have been found to have relevance in their application to the Toronto case in chapter two. This chapter has provided an analytic framework for these questions, based in organisational theory, which encompasses the literature on the relationship between organisational structure and environment. The following chapter discusses methodological issues relevant to the study of organisations and presents a strategy for addressing the research questions.