CHAPTER VI

EXCERPTS FROM INTERVIEWS

6. 1. Introduction

6. 2. Relationship between hospitals and universities

6. 3. Summary
6.1. Introduction

Firstly, respondents identified the pressures coming from investigators needing specialised assistance such as ethical advice, budgeting or formal approval to perform an increasing number of studies.

"This hospital has experienced an increased volume (of clinical research) and needs more structured management."

"There are concerns about compliance with regulations”

6.2. Relationship between hospitals and universities

In an interview with a respondent the relationship between hospitals and universities was described in this way:
"There are two common approaches: (1) Where the hospital is owned by the university, clinical research management is the domain of the university structure; (2) Where the university and the hospital operate as separate entities with distinct budgets, clinical research management is the domain of the hospital. The first approach makes it easier to manage activities, as the complexity of two separate organisational structures can create barriers."

One respondent spoke about the dual roles involved in managing the financial aspects clinical research between the university and the hospital:

"The hospital treats the university like any other customer. Research costs are charged to a special account number linked to a study. This creates a vast bureaucracy to run the accounts. Dual reporting requirements create the need for compliance roles within both institutions."

The parallel hierarchies of many hospital and university structures are observed to have overlapping clinical and academic roles. This situation was highlighted by the confusion evident in responses regarding the employing organisation.

"This is a branch of a relatively large organisation which is hospital based. We are university based. The two different bureaucracies have very different goals and objectives, which impact on effectiveness."
"The hospital infrastructure consists of an R&D Committee comprised of senior management, such as the Medical Director, Nursing Director and financial managers. This group meets quarterly to set the strategic direction for research. This formal structure emphasises the importance of research in order to be a thriving organisation on the forefront of health knowledge. This strategy is maintained to enhance recruitment and retention of staff and to attract external funding."

"Reduced morale, less R&D, we may lose good researchers to academic/commercial institutions. "Own account" (i.e. not externally funded) research will "go underground" and put pressure on clinical services."

Regardless of the adopted configuration, the elements of clinical research management identified by respondents as critical for clinical research management were consistent. These included organisational control, formalisation, standardisation, centralisation and specialisation.

"Clinical research requires an institutional infrastructure that provides a strategic vision for the research workforce."

"For me, the most crucial elements of clinical research management are good specific funding management, support structures, regular critical appraisal and evaluation of status of projects and staff.”
"For me, the most crucial element of clinical research management is the development of an infrastructure, with clear policies, protocols and support from key people."

"For me the most crucial element of clinical research management is the education of all the people involved with the study, including the financial aspects."

Clinical and academic researchers also compete for priority in terms of hospital resources, such as access to patients, facilities and equipment. In other words, researchers and managers serve different missions with respect to the AMC. Managers concentrate on fiscal and risk matters while researchers are concerned with generating and testing hypotheses. One clinician described the situation in these terms:

"One of the difficulties in getting clinical people to come forward with research is the in-built prejudice in a peer-review process dominated by academic researchers."

"It is important that research reflects what the services need and want rather than academics."

"The focus of the investigators is on the science, while the focus of the institution is on financial and risk issues."

"There is little or no communication at high level management owing to lack of time. Staff members are resigning over frustration.”
One respondent further elaborated on the effect that the business efficiencies of managed care have had on the autonomy of professionals involved in clinical research:

"Universities have a long tradition of academic freedom and faculty autonomy, whereas hospitals and health systems are more market-driven and corporate in their structure and behaviour. These differences in structure and culture create tension. Unless you have someone within the hospital system that is dedicated to clinical research management, there will be tensions and barriers. With less money available for clinical research, Department Heads are no longer able to facilitate the interface between the clinical and research missions, as they have in the past. Increased centralisation in hospitals has reduced the degrees of freedom available to the DCs in the reporting structure."

Another respondent described the attitude of professionals with regard to academic freedom in this way:

"The biggest challenge is keeping track of undisclosed studies done informally by practitioners who don't see the need to declare what they are doing, not from a malicious point of view (well, rarely), just not seeing how their little project could be important enough to be recognised."

6.3. Summary
These comments from a managerial and administrative viewpoint acknowledge that the professionals are the 'key people' in the research management process.