CHAPTER VII

SUMMARY OF FINDINGS, RESULTS AND CONCLUSION

7.1. Introduction
7.2. Summary of Findings and Results
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7.1. Introduction

In this chapter, the researcher has presented the summary of findings and Results, suggestions and conclusion of the study and also discussed the Strengths of the current research and Scope for Further Research. The researcher has given various suggestions for the betterment of organisational structure for clinical Research in Academic medical centre Kerala and policy makers.

7.2. Summary of Findings and Results

This study involved three phases of study. The methods employed in the first phase involved the review of secondary sources such as journal articles and websites in order to obtain background information related to the environment and structures for clinical research management in AMCs. In each AMC studied, new Government policies on healthcare funding have been introduced in an effort to contain the cost of
healthcare. The data presented in chapter four also suggests that AMCs have experienced the flow-on fiscal pressures from these policies to contain their health services costs. The introduction of managed care and changes to the public health systems in the AMCs appears to have had a flow-on effect on clinical research in several ways.

Firstly, the amount of time available for clinicians to undertake research appears to have been reduced and clinical hours increased. This could reduce the AMCs overall capacity to perform research.

Secondly, AMCs have undergone some form of restructuring, whether through mergers and acquisitions or through government policy changes. The data indicate that this may have improved the research capacity of AMCs by expanding the networks and patient base.

Thirdly, the fiscal pressures on AMCs appear to have prompted to develop and promote clinical research capacity in order to attract revenue, whether through public grants or commercial contracts. Another fiscal driver for research that appears in the data is the cost savings in the form of improved patient outcomes. Finally, fiscal pressures on AMCs and other healthcare providers appear to have increased the degree of organisational scrutiny that is applied to the financial risks and obligations involved in clinical research.
The environment for clinical research has also changed in recent years. The study data suggest that advances in biotechnology have been driving the increased demand for commercially-sponsored clinical trials as new medicines and devices seek regulatory approval for their marketing and sales. The management of regulatory requirements for clinical research, especially with respect to human experimental protection and organisational systems of fiscal accountability, are reported in the data from all countries as important tasks.

The data in phase one indicate that the majority of clinical research takes place within academic medical centres. However, the data also indicate that, while the number of research protocols is fairly good, the overall number of commercial research conducted by Central Government AMC is lower than that of the Private AMC.

In terms of the first research question, the environment for clinical research in AMCs has been dynamic both with respect to internal structural changes and external environmental demands. The data suggest that the financial and regulatory demands of modern clinical research have facilitated the establishment and development of committed infrastructure for managing clinical research in AMCs.

The formal structures reconstructed from the survey responses provide specific comparisons between the positions, roles and tasks involved in clinical research
management. These formal organisational structures for clinical research management can be characterised by three models.

In the first model, the management positions and tasks are embedded within the structure of a university, where dedicated sub-units manage the specialised aspects of clinical research, in the form of a function based organisation structure. This is an established and predominant structure for clinical research management in Central Government AMC and at the core level for other AMCs.

In the second model the processes are similarly embedded, but into the hospital structure and not into the university structure. Mostly, this is a process-based structure. This arrangement was observed in State Government AMC.

The third model is the research institute, which specialises in the management of clinical research and works between the hospitals and universities. These organisational entities are separate from the university and hospital. The research institute provides a dedicated infrastructure and resources for managing numerous and complex clinical trials, and frequently employs university and/or hospital staff to conduct research, as well as their own staff. This is a project-based structure. This model is observed in the Private AMC.

Respondents viewed the development of infrastructure, including policies, procedures and reporting relationships, as a critical success factor in the management
of clinical research. Infrastructure refers to formalised and dedicated sub-units embedded in the organizational structure of the university, hospital or research institute. The reasons why these are considered so vital included better organisational control, particularly in managing legal and financial risks. The centralisation of these activities was also believed to contribute to process efficiencies, the development of specialised training structures and a unified approach to sponsors. This necessitated the formulation of a structure for AMC, justifying the need for the present research.

The survey findings suggest that the formal structures for clinical research management in AMCs are different in diverse AMCs, which appears to support the phase one data. However, the general trend indicated by these findings is that AMCs have, in recent years, either established dedicated structures, policies and procedures for managing clinical research or have re-developed existing specialised structures. This also further justified the present research.

As the number of clinical trials increase, particularly commercially sponsored studies, the greater the need to manage both the risks and rewards of these activities at an organisational level.

The survey and interview data have also provided information regarding the specific task activities associated with clinical research management. The results indicate that the list of ten tasks, derived from the phase one findings, is a valid
representation of clinical research management activities, although some tasks may be more important than others.

For example, budgeting and monitoring projects were seen as more important than tracking publications and managing intellectual property. There is also variance in how respondents perceived their organisation's effectiveness in relation to these tasks.

Descriptions of the professional tensions and organisational boundaries that impact on clinical research management were common in the survey and interview responses. Professional tensions exist between practitioner groups, such as doctors and nurses, between departments and between clinically-based and academically-based researchers. In addition, the barriers that exist between researchers and management and between the organizations involved have also been described in the data.

Respondents acknowledged that these pressures and hurdles have the prospective to reduce the effectiveness of the organisations' infrastructure for clinical research management. The most common advance taken to alleviate these negative factors is the implementation of informal structures and mechanisms, such as liaison roles, committees and task forces, which transcend professional and organisational boundaries and enable communications between these groups and organisations. These liaison elements were described as a means to reduce barriers to effective clinical research management.
<table>
<thead>
<tr>
<th>Activities</th>
<th>Central Government</th>
<th>State Government</th>
<th>Private</th>
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<tbody>
<tr>
<td>Processing applications for approval of clinical research (other than ethical review)</td>
<td>Principal Investigator</td>
<td>Principal Investigator</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>Budgeting of projects</td>
<td>Principal Investigator</td>
<td>Professor / Asst. Prof</td>
<td>Professor / Asst. Prof</td>
</tr>
<tr>
<td>Approving research project contracts</td>
<td>Controller &amp; Registrar</td>
<td>Director</td>
<td>Director</td>
</tr>
<tr>
<td>Granting final approval for projects</td>
<td>Secretary, Funding Agency</td>
<td>Secretary, Funding Agency</td>
<td>Secretary, Funding Agency</td>
</tr>
<tr>
<td>Daily project management</td>
<td>Principal Investigator</td>
<td>Professor / Asst. Prof</td>
<td>Professor / Asst. Prof</td>
</tr>
<tr>
<td>Financial reporting for projects</td>
<td>Principal Investigator</td>
<td>Professor / Asst. Prof</td>
<td>Professor / Asst. Prof &amp; Accounts Officer / Project Cell</td>
</tr>
<tr>
<td>Human resource management for projects</td>
<td>Project Management Division</td>
<td>Project Cell</td>
<td>Project Cell</td>
</tr>
<tr>
<td>Monitoring quality of clinical research (e.g. Govt. Health Dept.)</td>
<td>Funding Agency</td>
<td>Funding Agency</td>
<td>Funding Agency</td>
</tr>
<tr>
<td>Tracking publications</td>
<td>Principal Investigator and Funding Agency</td>
<td>Professor / Asst. Prof and Funding Agency</td>
<td>Professor / Asst. Prof and Funding Agency</td>
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</table>
Table 7.1 inferred that the key responsibilities within the organisations have been assigned according to their positions held and the authority delegated to the employees and ensured a clear cut demarcation of job roles to strengthen role clarity by avoiding role ambiguity. The Principal investigator play a vital role in the research management structure in any AMC irrespective of the sector by processing applications for approval, preparing budgets of projects, daily project management and financial reporting for projects. This information makes the other senior officers to give approvals in various levels. In the Central Govt. Controlled establishment the Controller/Registrar initiate the regulatory approval for the project in consultation with funding agency and concerned authority in Govt. And in other two sectors the same is initiated by the Director. The principal investigator and funding agency track the publications and also the funding agency keep monitor the quality of research in regular interval. The Project Management division take care of the HR management in Central Govt. Sector where as the Project cell mange the same in state and private sector. The Financial reporting is performed by the Principal Investigator in Govt. Sector whereas the same is done in consultation with an accounts officer in Private sector. Irrespective of the sector the concerned institution manages the Intellectual property in case of new inventions otherwise it will be managed by the funding agency. The structure is more or less
identical in nature in all the sectors except the difference in positional names. In Govt. Sector we can find a quality and quantity enhancement oriented structure where as in the private sector along with the same orientation cost effective orientation is also evidential.
Table 7.2 shows that in all the organisations activities related to Intellectual property management have an excellent importance and carried out with due effectiveness. In Central Government controlled Organisation activities like Processing
applications for approval of clinical research, Budgeting of projects and Financial reporting for projects also have due importance and carried out with due effectiveness and other activities have been viewed very good except Approving research project contracts and Granting final approval for projects which were rated fair with respect to their importance and effectiveness in the Clinical research process. In State Government controlled research Organisation except the activity mentioned above all other activities have been commonly opined as Very Good and Good with respect to their importance and effectiveness in the Clinical research process. In the private organisation all the activities related to research management were viewed excellent and very good by the respondents with respect to their importance and effectiveness in the Clinical research process. Basically it shows a comparatively higher level positive attitude among the respondents towards the clinical research activities in the private sector AMCs.
<table>
<thead>
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<th>Central Government</th>
<th>State Government</th>
<th>Private</th>
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<tr>
<td>Processing applications for approval of clinical research (other than ethical review)</td>
<td>Very Important</td>
<td>Very Important</td>
<td>Very Important</td>
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<tr>
<td>Budgeting of projects</td>
<td>Very Important</td>
<td>Very Important</td>
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<td>Human resource management for projects</td>
<td>Very Important</td>
<td>Very Important</td>
<td>Very Important</td>
</tr>
<tr>
<td>Monitoring quality of clinical research (e.g. ICH-GCP)</td>
<td>Important</td>
<td>Very Important</td>
<td>Very Important</td>
</tr>
<tr>
<td>Tracking publications</td>
<td>Less important</td>
<td>Very Important</td>
<td>Very Important</td>
</tr>
<tr>
<td>Intellectual property management</td>
<td>Very Important</td>
<td>Very Important</td>
<td>Very Important</td>
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Table 7.3 depicts that in the Central Government controlled Organisation it has been perceived that other than activities like Daily project management and Tracking publications, all other activities have equal importance, whereas in the State Government controlled Organisation it has been perceived that other than activities like Approving research project contracts and Granting final approval for projects, all other activities have equal importance. At the same time in the private organisations except Approval of research project contracts all other activities have equal importance. However any slight discrepancy in these activities will have strong ultimate percussion on the quality output of the research. It has been commonly perceived that it is always better to maintain an optimum possible importance allocation strategy to all the activities so that to ensure the desired quality and quantity in research activities in Clinical Area.
Table 7.4 shows that in all the organisations all the financial related activities and granting final approval of the projects have been assigned essential relative importance.

In the Central Government controlled Research Organisation activity related to Intellectual property management also assigned essential relative importance. In the
state Govt controlled Research Organisation the activities like Approving research project contracts and Monitoring quality of clinical research have got great importance and effectiveness and are quiet essential to ensure smoothness, quality and quantity of the research activities in the Organisation. In private Organisations the daily project management is rated moderate importance, tracking publications and intellectual property management were rated important and the rest of the activities were rated essential by the respondents of the private sector AMCs. In the Central Govt controlled Research Organisation Processing applications for approval of clinical research, Approving research project contracts and Monitoring quality of clinical research have moderate relative importance in overall comparison of the activities. At the same time Human resource management for projects and Tracking publications have been given less important in the overall flow chart of the research procedure and Daily project management is having trivial priority in the process, just because of the fact that daily reporting is a time wasting and futile effort and a regular interval can be structured for this to ensure the total quality management in the research procedure. It has been strongly felt that the attitude of the respondents and the structural security within the organisations have a great influence in the relative importance assignment to various activities in the overall flow chart of the research procedure.

With the aid of data collected in the three phases, the researcher arrived at a function based process structure that would be suitable for AMCs.
Figure 7.1

Proposed Process Based Functional Structure

Institutional Governing Body

Hospital Governing Body
- Doctors

Dean of Medical Institution
- Research Governing Body
- Dean of Medical Research
- Principal Investigator
- Research Project Co-ordinator
- Project Team – Process I

Academic Governing Body
- Professors
- Funding Section
  - Grants Office
    - Funds Co-ordinator
      - Financial Advisor – Process I
7.3. **Conclusion**

No formal research has been published that describes how clinical research is organised and managed in academic medical centres. Nor have there been studies conducted that compare the environment or structures for clinical research in AMCs in different countries (Candace, 2003). This study has investigated these areas with the aid of a multi-staged analytical process involving three phases and techniques of data collection and analysis. The findings from this study characterise the environmental context of clinical research and AMCs as well as the formal and informal organisational structures involved in clinical research management.

Clinical research is a traditional function of academic medicine. It is a complex activity that requires the trans-organisational interaction and co-ordination of multi-disciplinary professionals and other stakeholders. The organisation and management of clinical research is important for managing both the risks and rewards inherent in these activities. This study has explored the contextual factors of modern clinical research and has described the formal and informal structures and mechanisms that used to manage clinical research. Similarly to the concept of yin and yang in Chinese medicine, these two types of organisational structure appear as simultaneously complementary and opposing while nurturing the whole. It is hoped that these findings will generate further questions and avenues for future research in this challenging area of management.
7.4. **Strengths of the current research**

Firstly, the multi-method investigative strategy proved useful for obtaining data from different sources, using a variety of data collection techniques.

Secondly, this study has incorporated representative data from Central Government, State Government and Private AMCs, which expanded the scope of comparison for AMCs both within and between AMCs.

Thirdly, this study has been conducted over three and a half years, providing the researcher with opportunities to present these research findings at two conferences and obtain valuable feedback from colleagues, and to reflect on the results.

7.5. **Scope for Further Research**

Future studies could extend to the analysis of formal organisational records, operating policies, incidents and events in order to understand the dynamics underlying the trends in clinical research management. In-depth case studies could explore the informal structures how professional power might be used to influence formal organisational structures. Using qualitative methodologies such studies could also explore the data within the frames and metaphors of these organisations. Specifically, the nature of the informal structures might best be explained through theoretical frames such as psychic prisons, political systems and professional symbolism. Another direction of study might also include an exploration into the development of a research ethos in clinical care environments and the role of the research manager as an