



COPYRIGHT AND USE OF THIS THESIS

This thesis must be used in accordance with the provisions of the Copyright Act 1968.

Reproduction of material protected by copyright may be an infringement of copyright and copyright owners may be entitled to take legal action against persons who infringe their copyright.

Section 51 (2) of the Copyright Act permits an authorized officer of a university library or archives to provide a copy (by communication or otherwise) of an unpublished thesis kept in the library or archives, to a person who satisfies the authorized officer that he or she requires the reproduction for the purposes of research or study.

The Copyright Act grants the creator of a work a number of moral rights, specifically the right of attribution, the right against false attribution and the right of integrity.

You may infringe the author's moral rights if you:

- fail to acknowledge the author of this thesis if you quote sections from the work
- attribute this thesis to another author
- subject this thesis to derogatory treatment which may prejudice the author's reputation

For further information contact the University's Director of Copyright Services

sydney.edu.au/copyright

A Qualitative Study Exploring the Role of Clinical Trials Nurses in Australia

Thilakavathi Chengodu
RN, BN, BHSc (Hon)

Sydney Nursing School
University of Sydney

March 2013

A thesis submitted for the degree of Masters of Philosophy
University of Sydney
Sydney, Australia

Declaration

I hereby certify that this thesis does not contain, without the appropriate acknowledgement, any material previously submitted for a degree in any university. I also certify that this thesis does not contain, without the appropriate acknowledgement, any material previously published or written by another person.

SIGNED:

A handwritten signature in black ink, appearing to be 'Stahl', written over a horizontal line.

ON: 11th November 2013

Acknowledgements

In undertaking this research I am eternally indebted to the participants, supervisors, colleagues, friends and family.

Firstly, I would like to thank the participants for sharing their experiences, reflections and precious time with me. Their belief in this research has truly carried me across the many years of my study. I thank you all.

I would like to acknowledge the support of both my clinical trial colleagues and clinical nurses who listened to my progress, challenged me, encouraged me and helped to keep me motivated throughout my study years. In particular, to Professor John Thompson who always had time for me. To my work colleagues, I thank you for your words of encouragement.

I started this journey with Professor Sue Armitage who guided me through the maze of qualitative research and ethics submission. Her philosophy of ensuring ethics application was approved in the first submission is something that I have practiced ever since. It would have been next to impossible to write this thesis without the help and guidance of my primary supervisor, Professor Kate White. Her support, invaluable advice and dedicated time during data analysis has brought me to the final product. I had the privilege of Dr Susan Jones's expertise in qualitative research and Dr Kathleen Scott's knowledge of pharmaceutical clinical research environment to aid in certain aspects of the thesis. I am especially grateful to Associate Prof Donna Waters for the time and shared wisdom that she imparted to me in the last few months. Thank you very much Donna for your time in reviewing and editing the thesis before the final presentation.

Thanks also for the support and encouragement from staff and students from within the School of Nursing at The University of Sydney. I thank them for listening to my presentations and giving me positive feedback.

To my family, who have shared this tumultuous journey and given their never-ending support. Thank you to my husband and children for affording me student status! I owe a deep gratitude to Sherry, John and Jennifer Skuja for editing my thesis as well as their unwavering support and belief in me to complete this research. Thanks to Debbie for editing my tables. Thank you to my wonderful friends who have always believed that I will complete this journey, Lee Anne for her bed and airport pickups and Margaret for all your time and belief in making this possible.

List of Associated Oral and Poster Conference Presentations.

Chengodu, T and Armitage, S. (2004). *Clinical trials nurse and their role in the informed consent process*. Poster presented at College of Health Sciences Conference, University of Sydney.

Chengodu, T and White, K. (2005). *Clinical trials nurse and their role in the informed consent process*. Paper presented at Cancer Nurses Society of Australia, 8th Winter Congress, Hobart, Tasmania.

Chengodu, T and White, K. (2005). *Clinical trials nurse and their role in the informed consent process*. Paper presented at 5th International Clinical Practice Development Conference, Hamilton, New Zealand.

Chengodu, T and White, K., Jones, S., and Thompson, J. (2006). *Clinical trials nurse and their role in the informed consent process*. Paper presented at College of Health Sciences Conference, University of Sydney.

Contents

Declaration.....	ii
Acknowledgements.....	iii
List of Associated Oral and Poster Conference Presentations.....	iv
List of Tables.....	vii
List of Figures.....	viii
Abstract.....	ix
Chapter 1: Introduction to Research Study.....	1
1.0 Introduction.....	1
1.1 Background to the Study.....	1
1.2 Clinical Trials Coordinators.....	6
1.3 Personal Experience of Clinical Trials Nursing.....	8
1.4 Research Question.....	12
1.5 Research Aim.....	12
1.6 Significance of the Research.....	12
1.7 Outline of the Thesis.....	12
Chapter 2: Literature Review.....	14
2.0 Introduction.....	14
2.1 Overview of Clinical Trials Research.....	14
2.1.1 Benefits and Limitations of Clinical Trials Research.....	18
2.1.2 Ethical Considerations and Governance in the Conduct of Clinical Trials Research.....	20
2.2 Clinical Trials Research in Australia.....	23
2.3 Research workforce in Australia.....	26
2.4 Literature Review of Clinical Trials Research Nurse Role.....	27
2.5 Elements of Clinical Trials Nurse Role.....	33
2.5.1 Range of CTN Job Titles.....	34
2.5.2 Clinical Trials Nurse Responsibilities.....	37
2.5.3 Educational Qualifications.....	40
2.6 Professional Issues.....	41
2.7 Career Pathway.....	44
2.8 Conclusion.....	47
Chapter 3: Research Design.....	49
3.0 Introduction.....	49
3.1 Hermeneutics Philosophy.....	50
3.2 Gadamer’s Philosophical Hermeneutics.....	51

3.3 Study Design.....	55
3.3.1 Study Setting.....	55
3.3.2 Study participants.....	57
3.3.3 Recruiting Participants.....	57
3.3.4 Data collection.....	60
3.4 Data Analysis.....	63
3.5 Rigour and Trustworthiness.....	64
3.6 Ethical considerations.....	67
3.7 Conclusion.....	68
Chapter 4: Understanding the Clinical Trial Nurse.....	69
4.0 Introduction.....	69
4.1 Being a nurse.....	71
4.1.1 Functioning within a professional and ethical nursing framework.....	77
4.1.2 Applying therapeutic knowledge and clinical skills.....	87
4.2 Conclusion.....	94
Chapter 5: Discussion.....	96
5.0 Introduction.....	96
5.1 Being a Nurse.....	97
5.1.1 Functioning from a Professional and Ethical Nursing Perspective.....	101
5.1.2 Applying Therapeutic Knowledge and Clinical Skills.....	105
5.2 Implications.....	109
5.3 Conclusion.....	111
Chapter 6: Conclusion.....	114
6.0 Introduction.....	114
6.1 Summary of Findings.....	114
6.2 Strength and Limitations of this Study.....	116
6.3 Further Research Recommendations.....	119
6.4 Recommendations for Practice.....	120
6.5 Conclusion.....	122
Reference.....	123
Federal Drug Authority. (2009) <i>Vioxx and Drug Safety</i> . Retrieved from http://www.fda.gov/newsevents/testimony/ucm113235.htm	124
Appendices.....	130
Appendix A: Interview questions for Clinical Trials Nurses:.....	130
Appendix B1: Participant Informed Consent for Clinical Trials Nurses.....	132
Appendix B2: Participant Informed consent for Medical Practitioners.....	133
Appendix C: Consent Form.....	134

Appendix D: Advertisement	135
Appendix E: Table 2.4: Summary of Empirical Studies on Role of Registered Nurses Working in Clinical Trial Coordination Roles.....	136

List of Tables

Table 2.1: Categories of Clinical Trials Research	16
Table 2.2: Clinical Trial Development Phases I-IV.....	17
Table 2.3: Summary of Systematic Literature Review, exploring Nurses working in Clinical Trials Research.....	31
Table 2.5: Responsibilities of Clinical Trials Nurse.....	34
Table 3.1: Clinical Trial Nurse Experience	59
Table 3.2: Principal Investigators’ Clinical Trial Experience	60

List of Figures

Figure 1.1 Number of Clinical Trial Notifications 1998-2011	5
Figure 2.1: Literature Review Process	28
Figure 4.1: Themes from Analysis of Interview Data	70

Abstract

This study investigated the role that registered nurses play in the conduct of clinical trials in Australia. Rapid expansion in clinical research in the last decade has led to a significant increase in the number of clinical trials conducted globally. This has led to an increase in the number of health professionals engaged in different roles within clinical trials research and practice, notably registered nurses. With their knowledge of disease and healthcare training background, an increasing number of registered nurses have transitioned from the clinical setting to clinical research, filling positions in trial coordination and management. The current literature describing the roles and responsibilities of nurses working in clinical trials is mainly anecdotal in nature with very little published original research.

The aim of this study was to explore the role of registered nurses in clinical trials from the perspective of clinical trial nurses and medical research principal investigators. Data were collected from ten registered nurses and ten medical practitioners from a range of clinical backgrounds using individual face to face interviews. Interview transcripts were analysed using Gadamer's hermeneutic methodology to identify and create themes that describe the reality of the role that registered nurses play in the conduct of clinical trials in Australia.

One overarching theme supported by two subthemes were identified that helped explain the role that registered nurses play in clinical trials. The overarching theme was 'Being a Nurse', supported by subthemes: 'Functioning within a professional nursing framework' and 'Therapeutic knowledge and clinical skills'. The findings revealed that registered nurses working in clinical trials research enacted their role from within their professional nursing framework applying their nursing experience and clinical knowledge in clinical trials research conduct and management. As well as this, key challenges in regards to their role in

the informed consent process, collegial support and establishing their identity within the broader nursing community were identified.

In conclusion, this study has provided an initial observation into the world of nurses working in clinical trials research. The results also highlight what may be necessary to guide and develop nurses to progress further within this role. There is a need to explore more around the role of clinical trial nurses and to define the scope of practice for nurses in this role. Moreover further work needs to be done in identifying competencies and standards for registered nurses using their specialist nursing skills within a research role.

Chapter 1: Introduction to Research Study

1.0 Introduction

Clinical trials research has seen rapid growth in both the number of studies and breadth of study areas. The expansion of international clinical trials research has led to increased infrastructure support, particularly staffing, and as part of this, specific roles such as the clinical trial nurse (CTN) have evolved. However, the role of nurses working in clinical trials research in Australia has not been formally defined nor explored in depth. This thesis examines the role of CTNs in clinical trials research in Australia utilising hermeneutic philosophical underpinnings.

In this chapter, a broad overview of the contribution of clinical trials research to healthcare is briefly discussed. The researcher's professional background leading to this research topic, the primary research question and an overview of the process that underpins this research is also presented. The chapter concludes with a brief outline of each of the other chapters, presented to provide an overview of the thesis.

1.1 Background to the Study

Clinical research is a key component of healthcare systems, contributing to the development of new therapeutic agents, new interventions, improving current clinical practices and sometimes revealing the deficiencies in these areas (Friedman, Furberg and DeMets, 2010). This was highlighted in final report of the Australian National Health and Hospital Reform Commission (2009), which stated that ongoing research contributed to the progress of health care, whereby research needs to be recognised, valued and integrated within the health system. Clinical research is fundamental and an important component of the health care system in Australia driving the development and improvement of more effective, evidence-based medicine. This is echoed in the final report of the National Health and Hospital Reform

Commission (2009, p32) stating, *‘To promote research and uptake of research findings in clinical practice, we recommend that clinical and health services research be given higher priority’*.

Clinical research is conducted using various methods. However, clinical trials are now at the forefront of clinical research methods used to evaluate therapeutic interventions (Friedman et al., 2010; Piantadosi 2005). Clinical trials research aims to test interventions and therapies to identify the best possible way to diagnose and treat disease in people, and consequently has become the preferred tool and methodological approach that underpins evidence-based research and practice (Friedman et al., 2010). Furthermore, the conduct of clinical trials impact in delivering actual outcomes to the population. The National Health and Medical Research Council (NHMRC) of Australia National Statement on Ethical Conduct in Human Research (2007) defines clinical trials as:

‘a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure which can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.’ p (32)

The National Health and Medical research Council (NHMRC) is Australia’s foremost expert body promoting the development and maintenance of public and individual health standards together under a single national organisation for the functions of research funding and development of advice (<http://www.nhmrc.gov.au/about/organisation-overview/nhmrcs-role>). NHMRC allocates its funding via grants and fellowships, with a majority of these being allocated to medical practitioners who conduct clinical research as principal investigators. Principal investigators have the responsibility to ensure that all tasks and requirements of

clinical trials research are met including ensuring appropriate staff skills and adequate personnel to conduct clinical trials (<http://www.ich.org>). Therefore medical practitioners play an important role in the employment and management of clinical trials research personnel.

Clinical trials research in Australia is conducted according to regulations set by the Therapeutic Goods Administration (TGA) and standards set by the NHMRC. The TGA is a division of the Australian Government Department of Health and Ageing, responsible for regulating and evaluating therapeutic goods including medicines, medical devices, blood and blood products (<http://www.tga.gov.au>).

Investment in clinical trials research in Australia has enormous potential for economic and health benefits for Australians. These include faster access to newly developed therapeutic or health service interventions, income to support research institutions and infrastructure, development of skills and expertise for Australian researchers and, enhancing the profile of Australian research in general (NHMRC Clinical Trial Center proposal to Clinical Trials Action Group, 2010; Medicines Australia and Pharmaceutical Industry Council Research and Development Task Force, 2010). Local and global pharmaceutical companies, as well as clinical and academic investigators initiate and conduct clinical trials research in Australia (Medicines Australia and Pharmaceutical Industry Council Research and Development Task Force, 2010). Australia has approximately 460 biotechnology companies actively involved in the development of human medicines, and more than 60 pharmaceutical companies and about 154 compounds are known to be in development in Australia (Medicines Australia and Pharmaceutical Industry Council Research and Development Task Force, 2010).

Funding for clinical trials research in Australia comes primarily from the pharmaceutical companies who invest approximately about \$1 billion a year in research and development of new and current medicines already on the market (Medicines Australia Occasional Paper

Series 2, 2011). Of this, at least \$630 million is spent on clinical trials research per annum (2011 Survey of Privately Funded Clinical Research Activity, February 2012). In contrast, the NHMRC funded about \$100 million for clinical and randomised controlled trials in 2012 (NHMRC Research Funding 2003-2012). Furthermore, the pharmaceutical clinical trials research industry employs almost 14,000 people around the country in a range of highly-skilled, high paying jobs (Medicines Australia, Occasional Paper 2, 2010). Of those employed in this industry, 72% have some sort of post-secondary education and 19% hold a Masters or PhD degree (Medicines Australia Member Economic Survey, 2009). The research and development investment of pharmaceutical industries is the third largest by area of business expenditure in Australia, behind the financial services and mining sectors (Medicines Australia, Facts Book 2, 2010). It is quite clear that the clinical research industry as a whole is of great economic value to the Australian economy.

Since the early 1990s the number of clinical trials conducted in Australian has grown significantly. Much of the early growth can be attributed to the introduction of the Clinical Trial Notification Scheme (CTN) which not only decreased the time taken to start a study in Australia (Bourgeois, 2010; TGA, 2001) but also introduced an accurate system of recording trial activity. It was mainly during this period that Australia established itself as a preferred destination for conducting high quality and cost efficient clinical trials because of advantages such as highly trained researchers, good trial start-up times, reliable recruitment, competitive costs and a world class medical system (Bourgeois, 2010). Figure 1.1 shows the number of clinical trials notifications to the TGA each year from 1998 to 2011 and is indicative of clinical trials research activity in Australia annually.

However, in the last five years, there have been changes in the global environment that have seen the cost of research and development escalating rapidly, which in turn has affected

Australia's standing as a preferred destination for conducting clinical trials research (Kirkman, 2010). Two other recent challenges facing Australia in conducting clinical trials are reductions in the speed of setting up a clinical trial and low patient recruitment numbers (Medicines Australia Annual Report, 2010). The reduced investment into clinical trials research and development in Australia is most certainly due to increased competition from India, China and Latin America where a larger population base provides higher patient recruitment and cheaper costs in setting up of clinical trials (Medicines Australia and Pharmaceutical Industry Council Research and Development Task Force, 2010).

Figure 1.1 Number of Clinical Trial Notifications 1998-2011

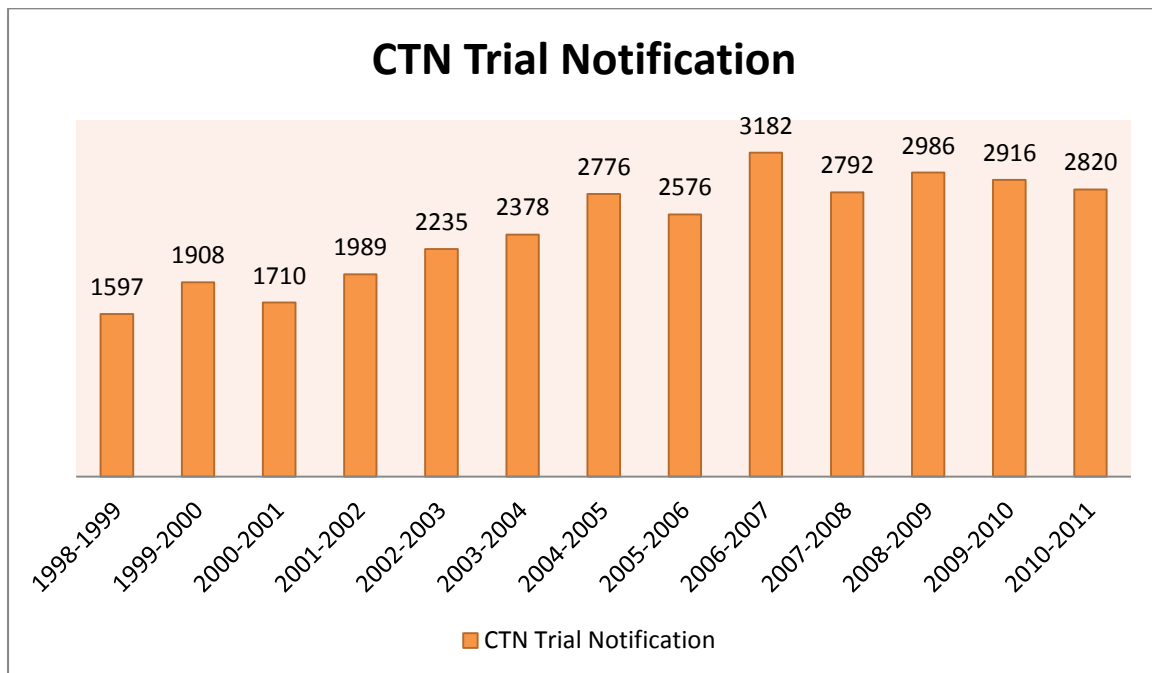


Figure 1.1 shows that the historical growth of clinical trials research in Australia had reached a plateau between 2007 and 2011 and may possibly show a reversal of trend. The potential loss to Australia in terms of economic value is a significant loss of clinical trial activity and investment with more than 2820 trials and projects registered in 2011.

To prevent a further decline in investment in clinical trial activity, initiatives need to be developed and implemented that specifically increase Australia's competitive advantage in conducting high quality research. Concomitantly, the Australian government has put in place a number of initiatives to encourage clinical trials activity in Australia which include investing in clinical research as part of its Nation Building Strategy and establishing an action group to identify and progress necessary reforms to secure Australia's competitiveness in the global clinical trials research sector. This will be further discussed in chapter two.

1.2 Clinical Trials Coordinators

With the sharp increase in clinical trials research activity over the last two decades (as shown in Figure 1.1), new roles within the industry have evolved. One of these is the clinical trial coordinator (CTC) role which involves the co-ordination and management of clinical trials. Despite a growing presence in the healthcare sector, not a great deal is known about the CTC role or those who perform it (Rickards, Roberts & McGrail 2006). The majority of research to date has been undertaken in North America and the United Kingdom, but two studies of the CTC role have been conducted in Australia (Roberts, Eastwood, Raunow et al., 2011; Rickard et al., 2006). CTCs play a key role in implementing and managing rigorous and ethically sound research in all clinical specialities. The role also encompasses education and has a range of caregiver/clinician responsibilities with trial participants. Therefore, CTC positions are much more than data collection and administrative support roles (Roberts et al., 2011; Hill and MacArthur, 2006; Jellen, Brogan, Kuzma et al., 2008). The position requires a high level of organisational skill with attention to minute details, excellent communication skills and sufficient clinical experience to be aware of possible implications or adverse effects associated with the treatment involved in the trial (Fowler and Stack, 2007).

The professional and clinical skills of registered nurses have been suggested as being

complementary to the CTC role and nurses are increasingly being employed into this role (Roberts, Eastwood, Raunow et al 2011; Bell 2009; Grady and Edgerly 2009; Yin 2008; Spilsbury, Petherick, Cullum et al., 2007 Rickard et al., 2006; Stephens-Lloyd 2004). Nurses have transitioned into clinical trials research in both pharmaceutical and academic settings and have become integral members of clinical trials research team (Hill and MacArthur 2006; Mueller 2001; Pelke and Easa, 1997). Despite varying position descriptions and job titles, nurses transitioning into CTC roles are generally acknowledged as health professionals displaying leadership qualities who are able to provide clinical expertise throughout the clinical trial process (Nagel, Gender & Bonner 2010; Poston and Buescher 2010; Stephens-Lloyd 2004). For the purpose of this study, nurses working specifically in clinical trials research as clinical trials coordinators will be addressed as clinical trials nurses (CTN).

In Australia, both government organisations and the pharmaceutical industry recognise that a highly trained workforce is required for the successful outcome of clinical trials (Petersen, 2007). It is difficult to obtain an estimate of the number of CTNs in Australia. This is partly due to the spread of CTNs across both private (pharmaceutical) and public (hospital) sectors, and no national employment database exists. However, it would be reasonable to assume, as some reports suggest, that the number of CTNs in Australia has increased over the last few years in line with the increased activity of clinical trials research (Rickard et al., 2006; Waller 2003).

Despite nurses embracing the CTN role, very little is known or reported about their involvement or contribution in Australian literature. As such, a greater understanding of the role of CTNs in Australia is considered important. This thesis aims to achieve a better appreciation and comprehension of the role that CTNs play in Australian clinical trials from

the perspective of registered nurses and medical practitioners working in clinical trials research. Medical practitioners' perspective is important to gain as they lead clinical trials research and are influential in recruiting CTNs. The researcher is a registered nurse working in clinical trials research. The following section outlines the personal experiences that led to this investigation of the role that nurses play in clinical trials.

1.3 Personal Experience of Clinical Trials Nursing

I was motivated to commence this project because of my professional experience working in clinical trials research. I started working in clinical trials as a registered nurse in the United Kingdom (UK). I worked in cardiology trials in the UK and oncology and cardiology clinical trials in Australia. I have found working in clinical trials research a rewarding, exciting and stimulating career. There were enormous variations across the three CTN positions I held over a period of eight years in terms of how my professional background as a nurse was utilised, the degree of contact with patients, my position as a clinical trials nurse, my role in the clinical trials team, and professional recognition of my career. My trip to the UK was decided after I had completed my Honours degree in nursing in Australia. I chose the UK for a number of reasons. Firstly, I noticed that nurses working in clinical trials research were more established in the UK, thus enabling me to widen my academic scope. Secondly, the nursing practice was similar to Australia and I did not need to sit examinations to prove my credentials.

My role as a CTN in the UK involved a range of trial related activities such as recruiting trial participants, contributing to the development of the study, providing feedback on how trial participants were progressing and often following up on trial participants' progress and outcomes. The follow up often involved discussion of participants' pathology results, education on general health and lifestyle and referrals to other health professionals if needed.

I was recognised as an integral part of the clinical trials investigation team and was published as the co-author of a paper in an international journal (Sastry, Daly, Chengodu & McCollum, 2007). During this period, my remuneration was set by the UK Nursing Council and it was set to a scale that recognised nurses working in clinical trials research.

On returning to Australia, I was successful in obtaining another position in clinical trials research and was struck by the contrast in how the role operated. I first worked in oncology trials before returning to cardiology trials. The oncology trial position was in a world-renowned unit in a large public hospital where international and domestic trials were conducted and I was offered the position due to my previous clinical trials research experience in the UK. The move to cardiology was motivated by my need to gain further experience in another clinical speciality. The key differences between these roles were my position title, the portfolio of responsibilities that I held, my involvement in trial recruitment and my remuneration scale.

In the oncology unit, my title was initially clinical trials assistant which was subsequently changed to clinical research officer without any changes to my job description. My role involved working with melanoma patients who had been recruited into an international multi-centre surgical clinical trial. I managed participants' follow up visits, often supporting them through various stages of their disease and treatments. I was responsible for data collection, nursing and research management of the patients I dealt with. The role necessitated a level of specialist knowledge of oncology and involved working closely with clinical nurses in oncology, allied health professionals, the radiology team, junior doctors and consultants. Often my role would overlap and incorporate that of clinical nurse, liaison, educator and researcher. The unit was a busy clinical and research centre with multiple trials being

conducted, but provided a supportive work environment and ready interaction with staff and other colleagues.

After three years working on oncology trials, I moved to a cardiology unit in a public hospital as a part-time clinical trials coordinator. It was a small unit compared to the oncology unit I had worked in previously, and had comparably smaller staff numbers, however my responsibilities here were greater than at the oncology unit. The description of duties involved managing a number of trials simultaneously and being responsible for monitoring the ethical requirements of these trials. The duties involved recruiting and managing participant follow up, liaising between pharmaceutical companies and various hospital departments as well as caring for patients, data collection and management, and attending audits and investigator meetings for new potential trials. Although it was a busy cardiology unit, there was little interaction with other health professionals in the unit and I often worked in isolation.

The key difference I noted between my position in oncology and cardiology was that at the cardiology trials centre, coordinators were encouraged to attend investigator meetings and conferences, and regular meetings were scheduled with the principal investigator to discuss trial and patient management. The key difference I noted between my positions in UK and Australia was the remuneration. In the UK, I was paid under a nursing scale that recognised both my nursing expertise and research skills, however in Australia this was not the case. Nurses working in clinical trials in Australia were (and still are) paid at the level that was deemed appropriate by the employer.

The remuneration scale for nurses in the UK is nationally set and monitored by a single governing body with varying levels of speciality and levels of clinical and academic

experience acknowledged. However, in Australia, the pay scale for nurses varies across the country. Different awards and agreements in workplaces, and in all health settings, determine the wages and conditions for nurses in Australia. Awards of Fair Work Australia provide the legal minimum for wages and working conditions in Australia but wages for nurses vary depending on the relevant State/Territory and the specific area of nursing (<http://anmf.org.au/pages/wages-conditions>). Having said this, there is no award for nurses working in clinical trials. In most states, CTNs are employed under a nursing award that is related to their clinical specialty and experience not their experience in clinical trials which is often determined by their employers. However, Victoria is working towards an award and pay scale for CTNs.

In Victoria, there is a pay scale for nurses working in research which is titled Research Nurse, graded at either level 3A or 3B with only 2 grade increments within the respective level (<http://www.anmfvic.asn.au>). The Victorian Association of Research Nurse with Australian Nursing and Midwifery Federation are currently in the process of classifying and streamlining the role and title (<http://anmfvic.asn.au/sigs/news>).

It was while working in cardiology that I began to reflect on my role as a registered nurse working in clinical trials and this led me to question if other nurses in similar roles to mine also had questions about their role. After making some inquiries I realised that many of my colleagues were also expressing dissatisfaction with their role as CTNs. They had similar questions about their scope of practice, their remuneration as well as their career pathway. I decided to pursue this matter further by reviewing available literature and discovered that there was very little research into the role of nurses working in clinical trials research and only a small number of studies conducted in Australia. There was a dearth of literature

concerning role recognition and no in-depth exploration of the CTN role. These findings led me to the primary research question for this thesis.

1.4 Research Question

What is the role of registered nurses in clinical trials research in Australia?

1.5 Research Aim

To examine and describe the role of nurses working in clinical trials research in Australia from the perspective of CTNs and medical practitioners working in this area.

1.6 Significance of the Research

As noted above, the Australian government and pharmaceutical industry has made significant investment in healthcare research and significant amounts of funding have been devoted to infrastructure and human resources supporting research. Furthermore, more clinical research is being conducted in Australia, particularly clinical trials, leading to an increase in the number of trial-specific and clinical trial coordinator roles. Although the CTC role is occupied by a range of health professionals, registered nurses are the largest group making a transition from the clinical setting to the trials setting. Despite this, research examining and describing the roles of CTNs is limited.

This research will describe the potential contribution of the CTN to the conduct and management of clinical trials research in Australia. The aim of this study is to facilitate better understanding of CTNs' role in Australia which in turn would assist with the development of the role among the nursing profession and potential employers.

1.7 Outline of the Thesis

Chapter two is divided into two sections. Section A explores current literature in relation to the clinical trials research industry and recent developments in clinical trials research in

Australia. This provides a critical context for the study presented in this thesis. Section B, presents a review of current literature focusing on the critical aspects of nurses working in clinical trials research and a critical analysis of the role of nurses in clinical trials research both in Australia and internationally.

Chapter three describes Gadamer's hermeneutic philosophy, the method chosen for this study, and its suitability in exploring the roles of clinical trials nurses. This chapter also outlines ethical considerations and how the study was conducted, including a description of the study design, participants, data collection and analysis and steps taken to ensure methodological rigour.

Chapter four explores the qualitative interpretation of the experiences of CTNs working in clinical trials research in Australia as emerging from the data analysis. Chapter five considers and discusses the findings of this study including implications of this research for nursing, while recommendations for further research and comments on the limitations of the study are presented in Chapter six.

Chapter 2: Literature Review

2.0 Introduction

To provide detailed background to this study, two areas will be examined in this chapter. First, recent developments in clinical trials research in Australia will be explored as this provides critical context for the study presented in this thesis. Clinical trials research is defined and described. The advantages and disadvantages of conducting clinical trials and the associated ethical considerations will be discussed. Finally, a brief overview of clinical trials research conducted in Australia is presented. Next, a literature review focusing on the critical aspects of nurses working in clinical trials research and a critical analysis of the role of nurses in clinical trials research both in Australia and internationally is presented. The critical analysis of the literature will include role recognition, educational qualifications, professional issues and career pathways.

2.1 Overview of Clinical Trials Research

Well-designed clinical trials encompass a specific type of methodological approach that enables researchers to test an idea, drug or intervention.

Friedman and colleagues (2010, p 2) define a clinical trial *'as a prospective study comparing the effect and value of intervention(s) against a control in human beings.'* Pocock (1983) describes a clinical trial as a term applied to planned experiments which involve patients and are designed to develop treatment for future patients with certain medical conditions. For the purpose of this research study, only clinical trials involving human beings will be considered. Research involving humans is regulated in many ways and at many levels. Clinical trials are guided and implemented according to a clinical trial protocol. The protocol contains information on scientific evidence that supports the trial, how the trial will be conducted including its design, eligibility criteria of the participants and the outcomes that are to be

measured. Clinical trial protocols are sent to regulatory bodies such as Clinical Trials Registries as well as to ethics committees for review and approval (Kerr, Knox & Robertson, 2008). Regulatory requirements in Australia apply through Commonwealth and state legislation, dealing with a range of matters such as the rules governing the conduct of clinical trials for therapeutic goods, radiation safety, use of human tissue samples and privacy of personal health information (Bloom and Frew 2009). In addition to this legislative regulation of research, a wider concept known as research governance directed to organisational frameworks and quality standards rather than just mandates and prohibitions is also practiced (NHMRC 2007; Bloom and Frew 2009). Research governance takes an expansive approach to the regulation of human research encompassing frameworks and systems over ad hoc policy making. Research governance promotes standards for the conduct of research, as well as regulatory requirements, mechanisms for dealing with research misconduct and definition of roles and responsibilities of all parties involved in research ensuring the promotion of quality research (Bloom and Frew, 2009).

Clinical trials research is funded by pharmaceutical companies, national research bodies such as the National Health and Medical Research Council of Australia, charitable foundations and private donations. Trials are usually conducted in hospitals, medical centres, universities, private clinical laboratories and research facilities. Individuals from varying specialities are involved in the design, conduct and management of clinical trials research. The clinical trials research team includes, but is not limited to, scientists, medical practitioners, nurses, other health care professionals, epidemiologists, statisticians, the sponsor organisation, ethics committees and patients and carers (Kerr, Knox & Robertson, 2008). Clinical trials are conducted in a wide range of clinical and disease contexts and vary in purpose, aims and objectives and design. Five broad categories, relating primarily to the study's clinical

objectives, are generally used for classifying clinical trials. These categories, summarised in Table 2.1 are: treatment, prevention, diagnostic, screening and quality of life trials.

Table 2.1: Categories of Clinical Trials Research

Treatment trials	Test experimental treatments, new combinations of drugs, new approaches to surgery or radiation therapy
Prevention trials	Evaluate approaches to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
Diagnostic trials	Conducted to find better tests or procedures for diagnosing a particular disease or condition.
Screening trials	Test the best way to detect certain diseases or health conditions.
Quality of Life trials or Supportive Care trials	Explore ways to improve comfort and the quality of life for individuals with a chronic illness.

Adapted from information accessed from clinicaltrials.gov. Accessed on the 21st April 2011

In addition, clinical trials research is often divided into four phases (I – IV) relating to the clinical development phases of a drug or device. The trials conducted at each phase have a different purpose and help investigators answer different questions (Table 2.2). Trials evaluating non-pharmacologic agents can be divided similarly and are split into phase II and III trials, with phase II being mainly a pilot study and phase III largely consisting of randomised controlled trials are where the intervention is assessed for its effectiveness and its value in clinical practice (Friedman et al., 2010).

Table 2.2: Clinical Trial Development Phases I-IV

Phase	Description	Example of Study Population
Phase I	Researchers test an experimental drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.	20-80 people; healthy volunteers or people with disease of interest
Phase II	The experimental study drug or treatment is given to a larger group of people with the disease of interest to see if it is effective and to further evaluate its safety.	100-300 people
Phase III	The experimental study drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments or placebo in a randomised controlled study design, and collect information that will allow the experimental drug or treatment to be used safely.	1000-3000 people
Phase IV	Post marketing studies to collect additional information including the drug's risks, benefits, and optimal use.	General population

Adapted from information accessed from clinicaltrials.gov. Accessed on the 21st April 2011

Despite the aforementioned breadth of clinical contexts and objectives, as well as the range of trial types, there are common characteristics of clinical trials which distinguish this research approach from other methods. Firstly, a clinical trial is a prospective study design in which participants are followed forward in time from a clearly distinct point at which they are identified, selected and observed from the point of initiation (Friedman et al., 2010).

Secondly, clinical trials are conducted in controlled environment, allowing for control of key variables such as the initiation of the intervention and measurement of covariates and confounders, helping to minimise bias (Piantadosi, 2005). Firstly, participants should be selected randomly from the population of interest. Randomisation in group allocation further strengthens the design by avoiding bias inadvertently introduced by selecting which participants receive which treatment (Friedman et al., 2010). Allocation concealment is

important for ensuring successful randomisation (Beller, Gebski & Keech 2002; Forder, Gebski & Keech 2005) and maintaining blinding after randomisation is important for avoiding bias (Forder, Gebski & Keech 2005).

Clinical trials are not merely observational studies but experiments that are measuring outcomes (Friedman et al., 2010). Therefore, clinical trials will always have some form of intervention, which may be a single or combination of diagnostic, preventive or therapeutic drugs, devices or procedures (Friedman et al., 2010).

2.1.1 Benefits and Limitations of Clinical Trials Research

Well-designed clinical trials have considerably advanced knowledge in both clinical practice and in understanding of the treatment of disease, benefiting both current and future patients (Kerr, Knox & Robertson, 2008). The testing of a new drug or intervention in a systematic way with bias minimised to the greatest possible extent enables researchers to interpret the results of a study with a greater degree of confidence. The phased approach to implementing an intervention in clinical trials research reduces risk to the participants builds on evidence and tests feasibility as the trial progresses through each phase, as illustrated in Table 2.2. Phase III and IV clinical trials are unable to be progressed without evidence from phase I and II to support the benefits and safety of an intervention (Piantadosi, 2005), thus reducing risk. Clinical trials are conducted in a highly regulated and rigorous way so that investigators can measure the effects of each treatment being tested on patients with a degree of precision and confidence (Friedman et al., 2010; Piantadosi 2005). In addition to this, the use of an internationally acceptable standard and clinical protocol enable replication of clinical trials so that results can be tested and confirmed in different populations (Friedman et al., 2010; Piantadosi 2005).

A critically important factor when evaluating new medicines and treatments through a clinical trial is the incidence of adverse effects or complications due to the intervention (Friedman et al., 2010). Sponsors and investigators are required to closely monitor the adverse effects of treatments according to strict regulatory reporting guidelines, which include immediate reporting of any adverse effects to the appropriate regulatory body and to ensure that all actions taken are recorded in clear and concise manner. This monitoring continues after the drug has become available for sale (Phase IV), with further identification of side effects sometimes leading to the withdrawal of a treatment or drug from the market. An example of this is the drug Rofecoxib (VIOXX®), which was withdrawn from the market in 2004 due to threatening and fatal side effects discovered through a prospective, randomised, placebo-controlled clinical trial conducted by the company that manufactured the drug (Federal Drug Authority 2009).

In Australia, the Therapeutics Goods Administration (TGA) administers the *Therapeutic Goods Adverse Drug Reaction Act 1989*, a legislation which provides a framework for a risk management approach allowing the community to have timely access to therapeutic goods which are consistently safe, effective and of high quality (www.tga.gov.au accessed 21st September 2011). In essence, the conduct of clinical trial research offers investigators and sponsors an opportunity to evaluate their product before and after it reaches the public, enabling efficient and safe delivery of new therapeutic interventions.

Limitations and challenges to conducting clinical trials research include the time that it takes to complete a clinical trial, the challenges of timely recruiting from a specified population and the duration of patient follow up. Regulatory and ethical approvals also take time and may be complex (Friedman et al., 2010; Piantadosi 2005). Other barriers are the cost of setting up and conducting clinical trials, the difficulty of studying rare outcomes in large

cohorts and issues with randomisation (Friedman et al., 2010; Piantadosi 2005). Issues with randomisation can include poor judgement in the choice of method, design errors in implementing the method and human error during conduct of clinical trials (Downs, Tucker, Christ-Schmidt & Wittes, 2010).

2.1.2 Ethical Considerations and Governance in the Conduct of Clinical Trials Research

The rapid increase in the number of clinical trials, particularly those sponsored by pharmaceutical companies and public funding by governments has placed clinical research and in particular clinical trials research under scrutiny (Friedman 2010; Piantadosi 2005). To ensure investigators preserve both integrity and accountability in the conduct of trials, clinical research should be underpinned by the imperative that investigators uphold and protect patients' safety and interests. The ethical framework guiding the conduct of clinical trials is shaped by both global and national guidelines. Research governance provides a framework for principles, requirements and standards for the conduct of clinical trials research. The framework aims to ensure that the scientific quality, ethical acceptability and safety of trials conducted in various institutions and organisations are preserved.

Institutions carrying out clinical research in Australia must have policies and procedures in place to meet national ethical, legal and research practice standards (NHMRC, 2007). Despite the stringent standards demanded by ethics and research governance frameworks, there are a number of previous clinical research studies involving blatant disrespect for patients' rights and welfare. For example, investigators in the Tuskegee study in Alabama, USA (1932-1972) studied groups of impoverished black males who had been diagnosed with syphilis and failed to give these patients penicillin even after penicillin was validated as a cure for the disease. In the New Zealand Cervical Cancer Experiments in 1970, treatment was withheld from women diagnosed with cervical cancer without their consent, monitoring of outcomes was

inadequate, and the study was not stopped when clinicians raised their concerns (NHMRC, 2007). These incidences have led to a global movement to ensure standards of practice are followed and maintained through the introduction of a comprehensive informed consent process (www.ich.org).

The current ethical framework governing clinical research began with the establishment of the Nuremberg Code. Following World War II and the discovery of unethical experiments conducted in Nazi concentration camps, the Code was promulgated with the goal of protecting human subjects in biomedical research. The next important step was the World Medical Association's adoption of the Declaration of Helsinki in 1964. The Declaration, which has since been expanded several times, defines ethical responsibilities of researchers using human volunteers in their research (www.wma.net). In 1990, the International Conference on Harmonisation (ICH) was started to progress international standards for conducting research, particularly in clinical trials, and for assessing the safety and efficacy of new drugs (www.ich.org). These global guidelines guide the current practice of clinical research in countries across the world by providing standards of ethical conduct and protection of patients in research.

In Australia, the NHMRC, Australian Research Council and Australian Vice Chancellors Committee developed the National Statement on Ethical Conduct in Human Research to guide researchers in ethical human research (NHMRC 2007). The development of the national statement reflects and supports global guidelines already in place. The National Statement specifies that participants must be accorded the respect and protection that is due to them. Furthermore, the research involved must be of benefit to the community (National Statement on Ethical Conduct in Human Research 2007). In addition to guiding the ethical conduct of research and the dissemination of research findings, the National Statement is

used by institutional ethics committees to guide the ethical review of research (NSECHR 2007).

The National Statement specifies that the relationship established by researchers and participants are based on values like respect for human beings, research merit and integrity, justice and beneficence which lead to trust, mutual responsibility and ethical equality (NSECHR, 2007). Respect for the individual or participant is reflected in the principle of informed consent, which incorporates the individual's right to select to be involved in the research (consent) and the need to be fully informed to enable them to make this decision. The process of consent allows the participant to make an autonomous decision in regards to participation that is required to be respected and adhered to by the clinical trials research team (Gallin and Ognibene, 2012).

Ethics and research governance play an integral role in ensuring that clinical trials research is conducted with participants' welfare being of utmost importance. Ethics committees provide advice and set guidelines relating to the conduct of clinical research involving humans as well as promoting debate on health ethics issues and monitoring international development in health and research ethics (www.nhmrc.org.au). Research governance ensures that standards of practice are maintained. Standards of practice are defined by the ICH and described by the term 'good clinical practice' (www.ich.org).

In 1996, ICH published a set of guidelines for good clinical practice which is currently used as the international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects (Guideline for Good Clinical Practice E6 (R1), 1996). Good clinical practice provides assurance to all parties concerned that the rights, safety and wellbeing of trial subjects are protected, consistent with principles that have their origins in the Declaration of Helsinki, and that

clinical trial data are credible (www.tga.gov.au). It is a major requirement of good clinical practice is to ensure that staff working in clinical trials research have achieved and maintain good clinical practice (www.ich.org and www.tga.gov.au). This is to ensure that clinical trials research are conducted safely and that data collection and results have credibility. The responsibility to oversee the conduct of clinical trials research is assigned to the investigator. In fact, within the Guideline for Good Clinical Practice E6 document, very little, if any is mentioned of the role a nurse plays in clinical trials research conduct despite the critical role that nurses play in the conduct and management of clinical trials research.

In summary, it is crucial that research is carried out ethically and scientifically to ensure the safety and welfare of participants. In Australia, ethical research conduct is mandated by a National Statement which is informed by a global framework of declarations and codes of conduct. Clinical trial researchers and institutions at which clinical trials research is being conducted are responsible for understanding and complying with these requirements.

2.2 Clinical Trials Research in Australia

Clinical trials research represents a key research activity in Australia with the clinical trials research sector worth approximately \$1 billion per annum to Australia with direct foreign investment of over \$450 million per annum (Clinical Trial Action Group, 2011). Conducting clinical trials research in Australia has led to economic benefits for the country with health research and development providing returns of 117% to Australia, exceeded only by mining (159%) and wholesale/retail (438%) (Access Economics, 2008). Investment in clinical research comes from both the private and public sectors with the main sources of funding for pharmaceutical research coming from commercial entities (Medicines Australia and Pharmaceutical Industry Council Research and Development Task Force, 2010).

The conduct of clinical trials research in Australia involves multiple sectors including the pharmaceutical and biotechnology industries, research institutions, hospitals and government departments. The NHMRC, Australia's peak body for supporting health and medical research, disperses considerable Commonwealth funding for clinical trials research (<http://www.nhmrc.gov.au>). The commitment of the government to research funding has helped facilitate the growth of clinical trials research. Other factors that have contributed to the growth of clinical trials research in Australia are the availability of Good Clinical Practice (GCP) trained staff able to manage and complete clinical trials research within time lines and a strict regulatory framework governed by the TGA (<http://www.tga.gov.au>).

The TGA is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products and evaluates therapeutic goods before they are marketed. The TGA also monitors products once they are on the market, as well as assessing the suitability of medicines and medical devices for export from Australia (<http://www.tga.gov.au>). The TGA continually monitors and evaluates the safety and efficacy of therapeutic products and manages any risks associated with individual products (<http://www.tga.gov.au>). To this effect, the TGA ensures that therapeutic goods available for supply and consumption in Australia are safe and fit for their intended purpose by ensuring *'pre-market assessment; post-market monitoring and enforcement of standards; and licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.'* (<http://www.tga.gov.au>). The regulatory framework that TGA has adopted when deciding whether to approve a medication for supply and the conditions that might be imposed on that approval is a risk-based approach to regulation (<http://www.tga.gov.au>).

In essence, both TGA and NHMRC work together to address protection of research participants, the safety and quality of research, privacy and confidentiality, financial integrity, legal and regulatory matters, risk management and monitoring arrangements and promote good research culture and practice (www.nhmrc.gov.au).

In response to a number of challenges facing the Australian clinical trials industry, the federal government established the Clinical Trials Research Action Group (CTAG) action group to identify and progress reforms for improving Australia's competitiveness in the clinical trials research sector (Department of Innovation, Industry, Science and Research, 2009). These challenges include the comparatively high cost of setting up clinical trials research in Australia compared to other countries within the Asia Pacific region, delays in ethical review, and patient recruitment targets not being met, especially in Phase III trials.

The CTAG proposed a number of initiatives to meet the aforementioned challenges. A key recommendation was the rapid initiation of a single ethical review process, the Harmonisation of Multi-Centre Health Ethical Review (HoMER), to minimise delays in ethical reviews. HoMER is a collaborative research project that was developed by the NHMRC to address the problem of multi-site ethical review. At present, the need to seek multiple ethical reviews across more than one hospital and state jurisdiction is a key problem and contributes significantly to delayed timelines for research. CTAG called for a national system of ethics reviews for multi-centre clinical trials in public health organisations by March 2012 (CTAG, 2011).

Other recommendations in regards to reducing delays include introducing a policy on clinical trials research that provides incentives to reach ethics and governance review within 30 days. For this service, sponsors would pay a defined additional amount to support increased efficiency and ensure a two months maximum timeframe for ethics and governance review

(CTAG, 2011) prior to trial commencement. However, Australia's national newspaper (The Australian) reported in May 2012 that changes have been slow to be adopted and implemented by the federal and state governments. Only three states, NSW, Queensland and Victoria have moved to streamline ethical review, and while single ethical review was achieved for study sites in public hospitals across all three states from early 2012, a national system is still not in place (<http://www.theaustralian.com.au>, May 22, 2012).

In its pursuit to maintain best health care delivery, the Australian federal government has now initiated a strategic review to ensure that Australia remains at the cutting edge of health care delivery. The McKeon Review *'will take into account broader Government policy, including the Government's fiscal strategy, and will focus on optimising Australia's capacity to produce world class health and medical research to 2020'* (<http://www.health.gov.au>). The Review will also pay close attention to a changing burden of disease, resources required for health research, and the dynamic nature of research - which includes infrastructure and better translation of research to clinical practice (<http://www.health.gov.au>). One of the matters that the review panel is looking closely at is how to attract, develop and retain a skilled research workforce which is capable of meeting future challenges and opportunities (<http://www.health.gov.au>).

2.3 Research workforce in Australia

The issue of developing and retaining a skilled research workforce is not new for Australia. Developing research workforce capacity was a recommendation from CTAG and was tabled by the NHMRC, Clinical Oncological Society of Australia (COSA), Medicines Australia and other organisations in their initial submission to both CTAG and the McKeon Review. The CTAG report provided a broad overview of the need for approaches to improve the timeliness of clinical trial approvals, the benefits of e-health for clinical trials, improving patient

recruitment and the level of support for clinical trials networks (<http://www.innovation.gov.au>) all of which can only be achieved with a strong skilled workforce. COSA in their comment on the 2011 Strategic Roadmap for Australian Research Infrastructure Exposure Draft (July 2011) insist that funding be secured to support the recruitment and retention of skilled clinical trials workforce which will include medical and science graduates, trial coordinators, data managers and biostatisticians. A skilled workforce is required if the process of ethics and governance in clinical trials research is to be closely observed and complied with. Furthermore, a highly efficient workforce will ensure that clinical trials research conduct continues to adhere to the standards of GCP.

In light of this call for investment in clinical research infrastructure, there are major implications for nursing. Anecdotal evidence suggests that nurses have held roles in clinical research that has combined the tasks of trial coordination with patient recruitment, education, data collection and patient care. Growth in clinical trial activity in Australia due to the recommendations of CTAG will ultimately lead to a demand for growth in recruitment and retention of nurses working in the clinical trials research field. Therefore there is a need to comprehensively understand and define the professional scope of nurses working in this role.

SECTION B

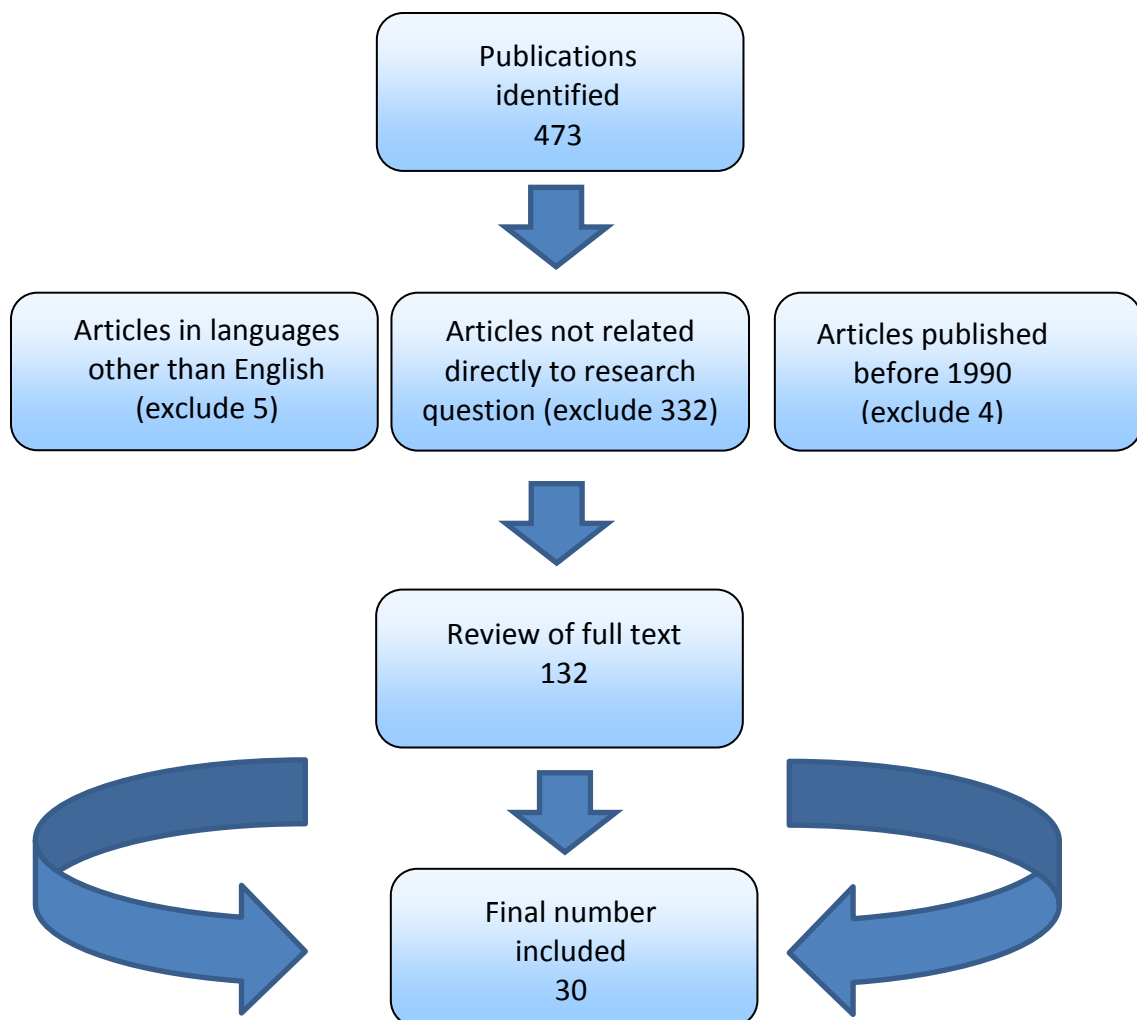
2.4 Literature Review of Clinical Trials Research Nurse Role

A literature review was undertaken to describe the current role of clinical trials research nurses in Australia, to explore professional issues surrounding this role and to identify gaps in the literature in regards to the clinical trials research nurse role. The literature review

provided a basis for the context of the interview questions that is part of the qualitative method for this research.

The process of conducting this literature review is outlined in Figure 2.1, followed by a detailed discussion of the role of clinical trials research nurses based on findings from the literature. This literature review will focus on the numbers of Clinical Trials Nurses or CTNs in the workforce, elements of their role, specific professional issues and career pathways.

Figure 2.1: Literature Review Process



The search strategies employed were designed to identify and collect as many relevant publications as possible for the review and used the following keywords: *clinical trials research nurses, clinical trials research, research coordinators, research nurses, clinical research nurse, clinical trial coordinators, data managers* and *nurses' role in clinical trial*, as well as appropriate combinations of these terms. A systematic search was carried out in four databases, CINAHL, MEDLINE, PUBMED and Google Scholar which yielded a total of 473 publications between 1976 and 2013 (Figure 2.1). This included five articles found using the find 'similar articles' and 'link to similar articles' functions when a related article in any of the databases was identified and a number of papers identified from citations in other journal articles as well as conference presentations.

An abstract review of the 473 publications was undertaken and it was noted that there were four articles discussing the role of nurses in clinical trials research prior to 1990. However, more interest is noted in the role after 1990, especially in North America where the bulk of articles were found. After excluding papers that were not directly relevant to the search question and five articles that were not written in English, a decision to also exclude four articles published prior to 1990 was undertaken because of the emergent nature the role before this time (Figure 2.1). The reference lists of the remaining articles were examined to identify any publications that were not detected in the literature search. Additional searches of the above databases using the names of the authors known to have published on the topic were also conducted.

Following the initial review, a total of 132 full text articles were retrieved and reviewed in detail. The literature regarding the role of the registered nurse in clinical trials research was of variable quality and lacked empirical contributions and a majority of the articles consisted of

expert opinion. Of the 141 papers reviewed, 25 papers were identified as being empirically based research for which questionnaires and surveys were used to gather data and five journal articles using systematic literature reviews to address the role of registered nurses in clinical trials research were retrieved. Of the final 30 studies and articles included in this review of literature, nine studies focused on the CTN role within particular clinical specialities, for example oncology. Others published from the 1990s and onwards discuss the role of CTNs more broadly; for example, issues of how the role fits into the clinical trial research context, career structure, educational needs and ethical responsibilities towards patients and trial management.

This review of the literature indicates a plethora of position titles used for nurses working in clinical trials research and include: research nurse, clinical research nurse, study coordinator, trial coordinator and data manager. The latter position titles clearly indicating that persons other than nurses occupy these roles. A brief and informal search for positions in clinical trials research such as the Australian employment website www.seek.com.au also produced various titles for jobs requiring nurses to coordinate trials. This finding was also repeated when searching for clinical trials research positions through health organisation and recruitment agency websites in Australia. The position title encountered most frequently was that of ‘clinical research coordinator’ or ‘clinical trials coordinator’.

Table 2.3 presents a summary of the five articles which used a systematic literature review method to explore the role of nurses in clinical trials research. One is from New Zealand, two from USA and two from UK; none are from Australia. Three of the authors conducted their review to ascertain if the role of the nurse in clinical trials research is comparable to that of

clinical nurse specialist while the other two reviewed literature to determine the definition and explore the role of nurses in clinical trials research.

Table 2.3: Summary of Systematic Literature Review, exploring Nurses working in Clinical Trials Research

Author	Year	Country	Description	Conclusion
Bell	2009	New Zealand	To define and describe the role of research nurses and to explore issues surrounding the within the context of New Zealand	The role of research nurses is in transition, needs career structure, education and training and building a network in New Zealand.
Bird and Kirshbaum	2005	UK	To explore the role of the clinical research nurse in cancer care and be considered at advanced practice	Advanced practice within clinical research nursing is possible and provides further level of career development that may facilitate movement between research and clinical practice
Ocker and Pawlik Plank	2000	USA	Evaluation of the research nurse role to develop and integrate the role within an oncology research program	Findings provide a framework for evaluating the roles of registered nurse personnel in a clinical setting
Raja-Jones	2002	UK	To compare the role of the clinical research nurse to clinical nurse specialist	No available empirical evidence examining the role of clinical research nurse in UK and how the role fits into clinical specialist nursing. There remains a lack of agreement to the definition and educational preparation of clinical nurse specialist.
Raybuck	1997	USA	Discussion of the multidimensional role of the research coordinator and the contributions that the clinical nurse specialist brings to the role of research coordinator	Advanced educational preparation of the research coordinator is needed and the role requires an advanced practice nurse with the ability to apply knowledge, skills and experience autonomously to complex health situations.

Table 2.4 (Appendix E) presents a summary of the remaining 24 studies that present empirical data. These were published between 1993 and 2012. Of the 25 papers, eleven studies used descriptive quantitative analysis, six studies used focus groups, three studies used interviews, two used both surveys and focus groups for questionnaire development, another used documentary analysis and two studies used a mixed methods approach. The topics addressed included: roles, responsibilities, career prospects, rewards and challenges of

position, job satisfaction, and research misconduct by research nurses. The sample sizes of these studies ranged from 9 to 312, with 20 of 25 studies having a sample size of less than 100 participants. These studies have been published in peer reviewed journals.

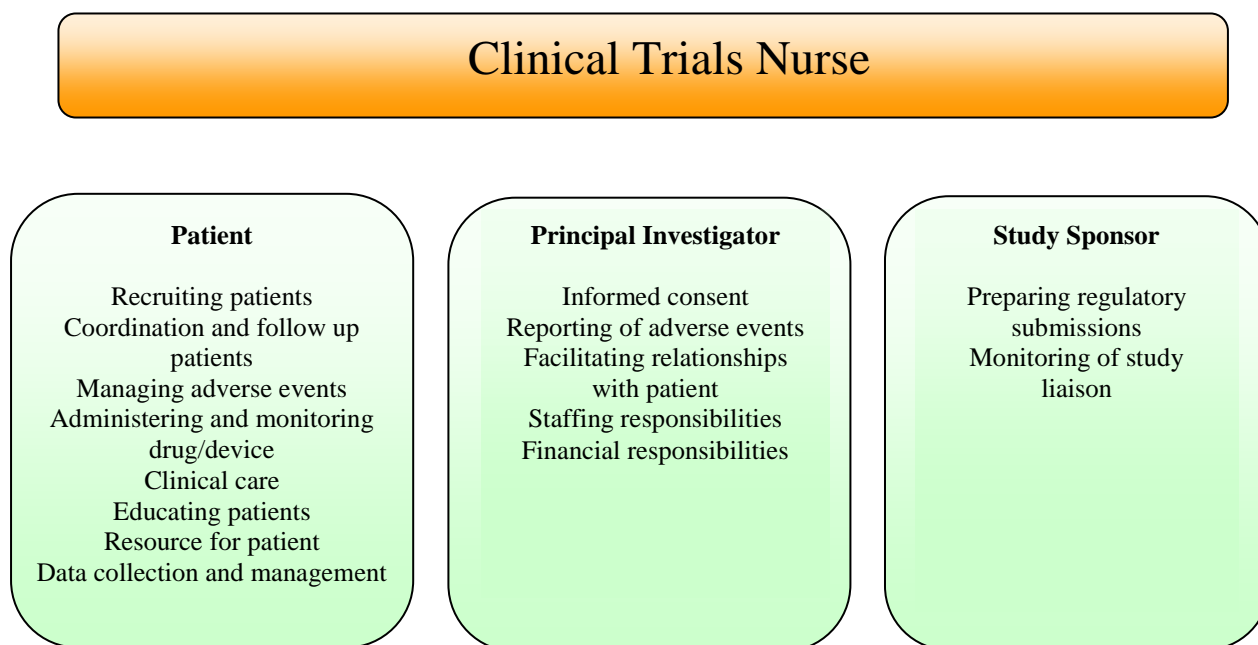
The participants in the research studies reviewed were always nurses in clinical trial coordination role except for three studies which included principal investigators, patients and other professional background in the role of clinical trial coordination. One, a study from South Korea which included principal investigators as participants in determining the roles, proficiency and qualification of registered nurses working in clinical trials research (Jeong et al., 2007). Another study, interviewed patients, principal investigators and registered nurses to investigate how the researchers and subjects who participate in clinical trials understand the contribution of nursing care to research (Easter et al., 2006). The third study conducted by Loh and colleagues, (2002) interviewed data managers whose backgrounds were varied health professionals.

2.5 Elements of Clinical Trials Nurse Role

The role of the clinical trials nurse role (CTN) has evolved significantly in the last 30 years from data collection to a more specialised role requiring specialised knowledge of managing and coordinating clinical trials (Oncology Nursing Society (ONS) 2010; Rickard et al., 2006; Hill and McArthur 2006; Raja Jones 2002; McEvoy et al., 1991). CTNs work in a wide range of clinical and research settings with roles that now encompass day to day data collection, complex study coordination and often leadership and management positions as well (ONS 2010; Bell 2009; Rickard et al., 2006; Bird and Kirschbaum 2005).

Several studies have systematically examined the activities performed by CTNs as described in Table 2.3 and Table 2.4 (Appendix E). The activities identified by these studies (summarised in Table 2.5) highlight the wide range of responsibilities in coordinating the day to day conduct of clinical trials and the attributes, knowledge and skills required for this role. Table 2.5 shows that the responsibilities of CTNs appear to focus on three main areas: the patient, the principal investigator and the conduct of the study (Study Sponsor). Another important trend noted from the literature review is the range of job titles and diversity of roles that registered nurses working in clinical trials research undertake (ONS 2010; Bell 2009; Rickard et al., 2006).

Table 2.5: Responsibilities of Clinical Trials Nurse



2.5.1 Range of CTN Job Titles

The findings of the literature review emphasise the diversity of the CTN role in terms of varying job descriptions and ambiguous job titles and roles (Nagel et al., 2010; Bell 2009; Rickard et al., 2006; Stephen-Lloyds 2004). The results of the review, supplemented by searching internet job sites, underscores the notion that job titles have not changed over time and contribute to making the progression and identification of the role challenging. The issue is further compounded by the use of generic titles, for example, ‘clinical trials coordinator’ – a role which can be filled by health professionals other than nurses. Therefore it is not clear how many nurses are in the CTN role in Australia and what their role actually entitles.

In Australian clinical trials, the actual title given to a nurse varies and may include research nurse, research coordinator, clinical research coordinator, research clinician, or clinical trials

coordinator. Regardless of the title, nurses employed to work in clinical trials develop, coordinate, and implement research and administrative strategies essential to the successful management of research conducted by principal investigators (PIs). Nurses perform a variety of duties involved in the organization, oversight, documentation, and compilation of clinical research data (Fowler and Stack 2007).

Rickard and colleagues (2006) reported 21 different job titles from 49 respondents in their study conducted in Australia and New Zealand. Nineteen participants were called Research Coordinator, six used specialty specific derivations such as ICU Research Coordinator, two were called Clinical Research Coordinator and six participants used the title Research Nurse. Other titles used were Manager, Officer, Fellow, Nurse, and Assistant. Four respondents mentioned using alternative or combined titles such as Quality Improvement/Clinical Trial Coordinator and one reported no formal title. In addition, 31% of participants in this study reported absence of a formal job description. The studies of both Nagel et al (2010) and Rico-Vilademoros et al (2004) also reflect the same variations as reported by Rickard and colleagues with respect to variation in position titles for nurses working in clinical trials research.

Other literature on role titles in Table 2.4 (Appendix E) mirrors the findings from the empirical evidence (Deave 2005; Raja Jones 2002; Loh et al., (2002); Mueller (2001); Xanthos et al., (1998); White-Hershey & Nevidjon, (1990)). Johnson and Stevenson (2010) and Deave (2005) both discuss how the term nurse researcher and researcher are used interchangeably. Deave (2005) defines the nurse researcher as someone who is based in a university department conducting research related to nursing who has research fellow status, while a research nurse is a nurse working in clinical research, coordinating and managing

clinical research. Johnson and Stevenson (2010) describe the differences between the two titles, stating that the skill set that is utilised and required are different between the two positions as CTNs not required to hold academic research qualifications.

In the Australian context, Waller (2003) outlines three definitions for research nurse and suggests that a nurse who is working on a particular project assisting the principal investigator in data collection and management involving patients on a pharmaceutical trial is comparable to a clinical trials research coordinator. However, in light of the findings of Rickard et al., (2006) reported above, the title of 'research nurse' appears to be a generic title used for nurses working in all clinical research settings.

However, the definition of the CTN role is further complicated by staff without a nursing background also filling roles in clinical research, often with the same titles (for example, clinical research coordinator) (Rico-Vilademoros et al., 2004; Loh et al 2002). The variety of job titles used indicates an ambiguous but potentially multi-faceted role that is neither fully understood nor able to be accurately attributed to health professional groups engaged in the role. According to the literature, this situation could lead to uncertainty in accountability and responsibility, as well as a poorly defined career structure for CTNs (Bell 2009 and Simpson 2006).

A significant number of CTNs have no job description according to the assessment of the literature. Rickard and colleagues (2006) and Simpson (2006) found that 31% and 12% of their respondents, respectively, had no job descriptions. Another study reported that 72% of its respondents had job descriptions, but only half of these were an accurate reflection of their CTN duties (Hill and MacArthur, 2006). Earlier studies (Ahern et al, 1993; Xanthos et al., 1998) report that original job descriptions did not reflect a number of duties carried out by the

CTNs. At this time, CTNs were not included in the planning stages of the clinical protocol and principal investigators failed to include some of their job description in the clinical protocol. It should be noted that these issues persisted over time, as indicated by articles, systemic reviews and research studies conducted over time. Recent studies investigating the role of CTNs in Australia by Wilkes and colleagues (2012) also report similar dissatisfaction by CTNs in regards to their job description and job satisfaction.

2.5.2 Clinical Trials Nurse Responsibilities

The review of the literature shows the broad categories of responsibilities that CTNs are involved in as depicted in Table 2.5. The table shows that CTNs are involved in three different aspects of their job which involve patients, study investigators and sponsors. Within each of these aspects there is a further breakdown of responsibilities. Generally, the CTN role was described as screening and enrolling patients, managing regulatory documents such as ethics submissions, data management and liaison with a variety of professionals including trial sponsors and maintaining the trial protocol as will be discussed in this section (Nagel et al., 2010; Catania et al., 2008; Rickard et al., 2006; Rico-Vilademoros et al., 2004; Loh et al., 2002; Mueller 2001; Xanthos et al., 1998; Ahern et al., 1993).

An earlier study found that the tasks and activities of nurses involved in European oncology trials were mainly related to patient care, and nurses were rarely involved in protocol preparation and review (Arrigo et al., 1994). Ahern and colleagues (1993) in their study conducted in North America discovered that the trial coordinators for a diabetes study were primarily responsible for recruitment, screening, adherence to protocol, medical management, education and training and administration (Ahern et al., 1993). The researchers further reported that although trial coordinators were responsible for all the above activities, the principal investigators did not anticipate such a wide variety of duties especially those

relating to medical management and administration duties. This probably reflects the fact that nurses in CTN positions absorbed these duties as part of their professional role. Although conducted in 1993, this study had already identified the need to develop a means to define characteristics, background, and training appropriate for the CTN position – definitions which are still lacking today.

A later Spanish study grouped CTNs' roles into five categories: administration, clinical monitoring, data management, statistics and research-related activities (Rico-Villademoros et al., 2004). These categories are similar to those identified by Ahern et al., (1993). Rico-Villademoros and colleagues (2004) reported that most of the CTNs' time in their study was spent on the monitoring activity which included patient registration, recruitment follow up, collaboration with clinical research associates, attending audits and reporting serious adverse events. This is similar to the division of roles reported by the findings of this literature review and outlined in Table 2.5 (Johnson and Stevenson 2010; Thomas 2003; Waller 2003; Haynes and Dada 2002; Mueller 2001; Ocker and Pawlik Plank 2000; McEvoy et al., 1991; Hodges et al., 1990; White-Hershey and Nevidjon 1990; Willems 1990).

Another study conducted recently within a paediatric oncology setting in the US reported subject recruitment, obtaining informed consent, data management and performance of the professional nursing role as the main role components of CTNs (Nagel et al., 2010). The survey design used for this study was able to capture and measure important nurse-orientated inputs such as in depth knowledge and cognition, critical thinking and decision making skills used in clinical trials research (Nagel et al., 2010).

Advocacy is another role component discussed widely in the literature reviewed. Davis and colleagues (2002) conducted a focus group to ascertain the role of study coordinators with 45 participants, of which 31 were nurses working as CTNs. The researchers identified three fundamental roles that pertained to the role of CTNs: subject advocacy, study advocacy and patient advocacy. Subject advocacy was the protection of individuals; study advocacy was related to gathering good quality data and advancing the goals of the research. Patient advocacy was reported as the main responsibility of the CTNs and relates to protecting the welfare of the patient throughout the study. The study also identified 19 general skills and 25 subcategories that CRNs perform. The skills and subcategories are similar to that of other studies reviewed here. Bell (2009) discussed the role of patient advocacy as being part of a broader nursing responsibility, and that acting as both study and patient advocate, CTNs are in a unique position to promote patients' rights and oversee the ethical conduct of trials. This unique positioning of the CTN is echoed by other authors (Fisher, 2006; Davis et al., 2002; Yin 2008).

A CTN is often responsible for screening, recruiting and enrolling patients into trials (Nagel et al., 2010; Johnson and Stevenson 2010; Hill and MacArthur 2006; Rickard et al., 2006; Bell 2009). CTNs identified this role as important because it involved information transfer to patients within the informed consent process and ensured patients' successful participation in trials (Nagel et al., 2010; Cantini and Ells, 2007; Stephens-Lloyd, 2004; Wright et al., 2002; Loh et al., 2002). The nurses' clinical knowledge in regards to patient procedures involved in clinical trials can assist with ethical submission and patient queries (Stephens-Lloyd, 2004).

It appears from the literature that CTNs play a role in recruiting patients which relies on a responsibility towards the governance and ethics of clinical trials research and maintaining the safety of patients/participants. The term advocacy is used frequently in the literature when discussing the role of the clinical trials coordinator in the informed consent process. However, it should be noted that the authors suggesting the term advocacy from the review are nurses themselves. The literature suggests that the role of the CTN is complex and multifaceted, involves patient and data management, the informed consent process as well as implementation of the study protocol and is seen by investigators as essential to the conduct of clinical trials research and the maintenance of GCP.

2.5.3 Educational Qualifications

This review of literature suggests that CTNs commence their roles with varied educational backgrounds and sometimes little knowledge or research experience is required prior to applying for these positions (Johnson and Stevenson 2010; Deave, 2005; Raja Jones 2002; Arrigo et al., 1994). A six month retrospective search and analysis of job advertisements placed under the research section of the Nursing Times in the UK demonstrated that there were little or no research requirements for research nurses' posts suggesting, no primary degree (eg Bachelor of Nursing) was required to apply for these positions (Deave, 2005). The study was investigating if any research knowledge and what type of qualification was required to qualify for CTN position. Other studies report that a majority of their respondents hold a minimum qualification of an undergraduate nursing degree up to PhD but not really provide a critical discussion in regards educational needs and CTN role development (Wilkes et al., 2012; Nagel et al., 2010; Rickard et al., 2006; Rico-Villademoros et al., 2004; Davis et al., 2002). Raybuck (1997) suggested that CTNs with Masters' Degree would bring combined research skills and advanced clinical expertise to the research settings and further stated that

all nurses in the role of clinical trials research coordination and management should pursue a research postgraduate to enhance their position as a CTN.

In summary, an assessment of the literature indicates that, while there is no consistent requirement for CTNs to have research experience prior to working as a CTN, most will have at least a bachelor degree, and some will have postgraduate research or clinical qualifications. However even basic qualifications vary between countries of practice, whereby a Diploma of Nursing constitutes registration for work as a Registered Nurse in some, while in other countries, a Bachelor of Nursing is a minimum requirement for practicing as a Registered Nurse. Therefore, almost all nurses transitioning into this role will have nursing expertise and professional practice which they will utilise in their role as CTNs.

2.6 Professional Issues

In the course of reviewing the literature, two professional issues related to the CTN role emerged: conflicts within the role and job dissatisfaction. These issues will be the focus of this section.

The previous section described how CTNs have a wide but poorly defined role within clinical trials research. The data and study management aspects of the role necessitate delivery of care and treatment in a complex and isolated context while demanding awareness and implementation of ethical and professional responsibilities (Cantini and Ells 2007; Hill and MacArthur 2006; Davis et al., 2002). Thus, fundamental to the role of CTN is the ability to balance patients' rights with the need to meet recruitment targets and to conduct good quality research at the same time (Fisher 2006; Hill and MacArthur, 2006).

The ICH guidelines which guide the conduct of clinical trials globally require that personnel working in clinical trials ensure ethical and safe conduct of clinical trials research. The

responsibility of overseeing clinical trials research staff falls upon the lead investigator which by type of clinical trials is often a medical practitioner. As these guidelines are taken as gospel by sponsors, it sets the tone for management, personnel and clinical research setting. Nurses, being a large part of clinical workforce have transitioned in the role of CTN, utilise their professional nursing skills and knowledge to ensure optimum outcomes of clinical trials. However, are not identified as being an integral component in the conduct of clinical trials research within ICH guidelines but instead delegated with other personnel such as data collectors and data managers (www.ich.org.au). This is where one of the many challenges faced by CTNs arises which is professional identity and role recognition.

Some authors described the ethical challenges that CTNs face, especially in understanding that conducting clinical trials research is different yet similar to their professional nursing role (Davis et al., 2002; Fisher 2006; Mueller 2001; Mueller and Mamo 2002). Fisher (2006) argued that CTN's construction of ethical practices (nursing ethics) is generated from their interaction with the patients and not from the requirements of institutional review boards or ethical principles related to research protocols, thus potentially contributing to conflict.

In the study conducted by Cantini and Ells (2007) in Canada, it is revealed that CTNs have a central position in trials, with complex relationships and much potential for conflict with other members of the research team. These authors reported that more than half of the respondents experienced conflict between their obligations to the participants and their duty to ensure successful completion of the study. The most common cause of the conflict was with the principal investigator who was also their employer (Cantini and Ells, 2007).

The common themes to emerge from these studies are the tension between the two roles of being a nurse and a trial coordinator, due to the overlap of roles and responsibilities and uncertainty. In addition, this tension is often not recognised by clinical specialist themselves (Ocker and Pawlik Plank 2000; Raja-Jones 2002; Stephens-Lloyd 2004). One author argues that CTNs are well placed to be future nurse consultants as these nurses are already equipped with a sound base for ethical, valid, high quality research techniques as well as excellent clinical skills which would facilitate a wide range of nurse-led health services research (Stephens-Lloyd 2004).

It can be concluded that the CTN role is complex and requires the nurse to achieve a balance between the complex requirements of the clinical trial and a professional nursing role. There is no literature discussing the conflict experienced by nurses in this role from an Australian perspective.

This review of the literature shows that there is more interest in wanting to quantify the work that CTNs do in order to better understand their role and provide more empirical evidence to justify and monitor role development. Recent studies assessing job satisfaction have reported that overall CTNs are satisfied with their positions but some CTNs report dissatisfaction in terms of recognition of work and stress related to increasing workload (Roberts et al 2011, Rickard et al., 2007; Nagel et al., 2010). This could apply to many nursing roles however.

Lack of recognition is a common theme in several studies and appears to be a primary source of dissatisfaction for CTNs. Davis et al., (2002) note that clinical trial nurses perform much of the work in clinical trials but remain unrecognised because principal investigators often receive the acknowledgements. Similarly, a survey of research coordinators (Rickard et al.,

2007) found that the main sources of dissatisfaction for research coordinators were remuneration and recognition; compensation for weekend work; salary packaging; career advancement opportunities and the availability of childcare facilities. However, coordinators were more satisfied with the structural aspects of their position, such as working business hours; flexible working hours and high levels of responsibility and control over their work. More recently, Wilkes and colleagues (2012) and Roberts and colleagues (2011) found that the work environment and lack of support and recognition for work undertaken by CTNs remained sources of dissatisfaction. Lack of recognition is also reported in the study by Hill and MacArthur (2006); one issue relating to this was CTNs reported feeling isolated because of the complexity of their role, leading to lack of understanding from clinically based nurses and other health professionals. Other issues which contribute to a sense of professional isolation include poor systems for job and performance appraisals, lack of understanding from nursing managers and little or no contact with other nursing colleagues (Wilkes et al., 2012; Roberts et al., 2011; Hill and MacArthur 2006; Rickard et al., 2006).

In conclusion the lack of acknowledgment of the role of CTNs as well as conflict between trial-related responsibilities and professional nursing responsibilities emerge as important professional issues. Furthermore, the absence of acknowledgment and recognition is cited as a cause of job dissatisfaction, underscoring the importance of addressing this issue in the future.

2.7 Career Pathway

The previous sections have discussed how a structured career pathway for CTNs is not apparent given the lack of job descriptions, numerous job titles and lack of recognition by colleagues. Literature based on both empirical evidence and expert opinion identified lack of

a career structure as a major professional issue experienced by CTNs. In addition to reporting lack of definition around job descriptions and titles, CTNs have also reported a lack of professional support, salary variation and limited specific educational and training support (Hill and MacArthur 2006; Rickard et al., 2006; Spilsbury et al., 2008; Stephens-Lloyd 2001; Thomas et al., 2008; Yin 2008). Research coordinators working in clinical trials within an intensive care unit reported being dissatisfied with the lack of training opportunities and perceived a limited career path (Rickard et al., 2006). Spilsbury et al., (2008) conducted a qualitative focus group study and also found that the clinical trial nurses reported a lack of confidence in their roles and noted the need for training and support to meet the various demands of the role. Based on the studies in this review, the latter point appears to be a key issue.

There is widespread recognition that the education and training of clinical trial nurses are insufficient and varied (Wilkes et al., 2012; Hill and MacArthur 2006; Mori et al., 2007; Rickard et al., 2006; Thomas et al., 2008; Yin 2008). As noted previously, CTNs are required to have a basic diploma or degree level nursing training in order to be registered as a nurse. Some will have postgraduate qualifications in a clinical specialty but very few will have postgraduate qualifications in research or previous research experience (Stephen-Lloyd 2004). As a result, there is an extensive 'on the job' training that clinical trial nurses undergo, often in the context of good clinical research practice. In Australia, this has been provided by the commercial sector for example, by companies such as Datapharma and Caledonian Training. These findings reinforce the need to develop formal educational programs to assist CTNs in their role. Thomas and colleagues (2004) suggest that pharmaceutical industry groups work with academic establishments to provide CTNs with efficient learning programs. It appears as that some progress has been made toward this suggestion.

In Australia, some universities now have programs that are tailored to the needs of clinical trial nurses working in clinical trials research, for example, the Master of Clinical Trials Research Practice that is now offered at the University of Sydney through Sydney School of Nursing. The University of Melbourne now offers the Specialist Certificate in Clinical Research (Clinical Trials Research Coordination) in conjunction with the Association of Regulatory and Clinical Scientists (ARCS). This program is aimed at all research staff, not only nurses. The Society for Clinical Research Associates (SOCRA) in the United States offers certification and credentialing processes for members of all health professions from all over the world working in clinical trials research (<http://www.socra.org/html/certific.htm>). Furthermore, establishing an organisation dedicated to supporting the educational and professional needs of CTNs has been suggested (Yin 2008; Mori et al., 2007). This would enable CTNs to meet socially, discuss and debate professional issues and create policies and a framework for their profession which will promote consistency in education, adherence to standards and professionalism.

An issue to consider when discussing educational preparation is how similar the CTN role is to an advanced nursing practice role (Bird and Kirshbaum 2005, Raja Jones 2002, Ocker and Pawlik Plank 2000). It has been argued that nurses working in the CTN role should be advanced practice nurses with a Masters' degree (Raybuck, 1997). For example, CTN skills and activities include working as an educator, clinician, researcher and consultant; these skills and activities are the same as those of a clinical nurse specialist (Raja-Jones, 2002). It was concluded by Bird and Kirshbaum (2005) that there is scope within the role of the clinical trial nurse to practice at an advanced level of nursing practice. Their analysis of published frameworks of advancing practice in nursing to explore the role of the clinical trials nurse in

oncology led to the conclusion that advanced practice is not defined by the role but by the level of skill to which it is performed.

This review has identified the complexity and diversity of the CTN role as well as the pressing problem of lack of recognition for this role and the lack of a defined career structure. Agreement on a formalised title, position description and the establishment of a clear pathway from novice to experienced CTN (Rickard et al 2006) can help address these issues. However, further research is needed given the relative paucity of published research in this field.

2.8 Conclusion

The findings of this literature review suggest that the role of CTN has evolved from one of simply collecting data and being a research assistant to now being an integral member of a clinical trials research team. The review has reported on how the role of CTN has developed to include and integrate organisational, clinical and ethical responsibilities. As well as this, CTNs have been described to have and implement the knowledge and the skills required in supporting and monitoring both the integrity of studies and the safety of patients. Further findings of the review, state that CTNs are responsible, in many instances, for the co-ordination of the trials on one or more sites. This involves protocol development, ethic approval applications, recruitment and consenting of participants in trials, to administering or assisting with treatments within the bounds of nursing practice code and evaluation of protocols.

In light of the complexities of the CTN role, there is a need for greater clarity of this role within nursing and research. There is no in-depth discussion into why nursing as a profession is crucial to the CTN role and what, if any, contribution CTNs make to the outcomes of

clinical trials research and also nursing research. Furthermore, inconsistent educational preparation and requirements for CTNs already in the position present a challenge. The lack of formal, structured courses is also a challenge for those nurses with an interest in becoming CTNs. The lack of a standard job description compounds the problem of establishing a career pathway for CTNs. As well as this, there seems to be a lack of collegial and social support for nurses working in this role.

This literature review has identified the need to start at the very beginning, with an in-depth exploration of the role of nurses working as CTNs. The aim of this study is therefore to identify the role of nurses working in clinical trials research by exploring the meaning and experiences of being a CTN from the perspective of both CTNs and PIs. Such an analysis aims to develop an understanding of the role that registered nurses play in clinical trials research with a view to making recommendations for their education and development of career pathways.

Chapter 3: Research Design

3.0 Introduction

This chapter provides a detailed description of the research design for this thesis. The first section of this chapter articulates the research design and its philosophical underpinnings. Specifically, it explains the choice of Gadamer's hermeneutics to inform the study and gives a brief history of philosophical hermeneutics before discussing the background to the formation of Gadamer's thinking and the important concepts of philosophical hermeneutics. The second section outlines the research process under the following sub-headings: ethical considerations, participant selection, data collection and analysis, and how rigour was achieved and observed in the study.

Methodology can be the strategy, plan of action, design or process lying behind the choice and use of particular methods, thus linking the choice and use of methods to the desired outcome (Crotty, 1996). Method is the technique or procedure used to gather and analyse data related to the research question (Crotty, 1996). It is important that the right methodology and method is chosen to answer the research question because it leads to better outcomes for the research and its contribution to the field of inquiry.

In selecting the research design to examine the role of the CTN, a number of factors were taken into consideration to describe, explore and examine CTN roles. It was concluded that this could be best achieved through interviews that would produce rich data where the CTNs' subjective experiences and perceptions and their thoughts and feelings would be obtained and analysed. The limited published research available at the outset of this study and the

expansion and evolving role of the CTN in the Australian context highlighted the potential benefits of using a qualitative research design. The underlying principles of qualitative research emphasise the need to both describe and understand people and provide insights into how people make sense of their experiences when researchers have little knowledge about the area of investigation (Rice and Ezzy, 1999).

Qualitative research inquiry seeks to explore and interpret the phenomenon under investigation through either critical or interpretive approaches (Schneider, 2007). Critical approaches seek to enable empowerment, emancipation and equality for research participants and to change or challenge existing social structures, for example action research or feminist research (Schneider, 2007). On the other hand, interpretive approaches focus on understanding the meaning of human experiences and actions, for example phenomenology, grounded theory and hermeneutics (Crotty, 1996). Therefore to gain an understanding of the role that registered nurse play in clinical trials research, an interpretive approach was chosen. Furthermore, a hermeneutic approach, based on Gadamer's philosophy regarding the prerequisites of understanding and existential interpretations is applied because, based on a hermeneutic perspective, the data that are compiled is dependent upon interpretation and any relevant insight or understanding stemming from the researcher's background.

3.1 Hermeneutics Philosophy

The word hermeneutics is derived from the Greek word 'hermeneuein', literally meaning 'to interpret' and from the noun, 'hermeneia' to mean 'interpretation' (Thompson, 1990). Hermeneutics was originally a set of techniques for interpreting written texts and was initially developed to translate biblical texts (Thompson 1990; Packer 1985).

The long history of hermeneutics can be traced back to St Augustine who used this as a method in interpretation of the Holy Scripture (Abulad, 2007). Friedrich Schleiermacher (1768-1834), who played a founding role in developing modern hermeneutics, introduced the concept of the language, stating that no understanding can take place if one does not think (implying the thinker) and one cannot think if there are no words (implying language) (Abulad, 2007). Schleiermacher highlighted that language is central to our understanding as everything is encased within the language that we speak, whether it is written or spoken, thus introducing the concept that hermeneutics could be applied with any text.

William Dilthey (1833-1911) further contributed to Schleiermacher's work by arguing that human beings come to understand their world through reflection and interpretation with other human beings, and they do this over time, bringing their traditions, history and language to their reality (Chadderton, 1997). Further to this idea, Dilthey considered a methodology, arising from Schleiermacher's interpretive inquiry, where each part is considered in relation to the whole and vice versa, thereby establishing the hermeneutic circle (Chadderton, 1997). The turn towards philosophical hermeneutics was influenced by the work of Martin Heidegger and later expanded by his student Hans-Georg Gadamer (1900-2002) who is credited with philosophical hermeneutics. It is this approach that has been selected for this study.

3.2 Gadamer's Philosophical Hermeneutics

Gadamer's work has been recognised as being central to the evolution of contemporary hermeneutic philosophy. Contemporary hermeneutics emphasises the human experiences of understanding and interpretation (Thompson, 1990). Gadamer describes the path to philosophical hermeneutics in his book *Truth and Method*. Gadamer (1989) posed the

question ‘How is understanding possible?’ emphasising the *meaning of being through understanding* as a philosophical question. He argued that there is no such thing as a method to describe understanding because method implies a scientific approach rather than an interpretive approach (Gadamer, 1975). Gadamer (1989) expanded on the work of both phenomenology and hermeneutics by Heidegger by offering an interpretive approach to understanding. Gadamer emphasised understanding, stating that it is situated in our historical, dialectical and linguistic tradition. Gadamer’s exploration of dialogue and conversation as a mode of understanding is central to the study of hermeneutics and in the conduct of interpretive inquiry which informs this research study.

Gadamer’s hermeneutics as outlined in his cornerstone work *Truth and Method (Wahrheit und Methode, 1989)* focuses on the linguistic nature of understanding. His hermeneutics philosophy examines the nature of understanding where he states that no particular technique or procedure of inquiry guides a researcher to understanding. Gadamerian hermeneutics concentrates on expanding horizons of understanding through dialogue, between people or between a researcher and texts. In a research context, the researcher engages with the text (written or verbal data) to make sense out of it and therefore develops an understanding *to and for* the text. In engaging with the text, the researcher brings to the process his or her background, knowledge and experience, in essence who the researcher is; Gadamer refers to this as tradition.

According to Gadamer (1989), tradition is not something that can be consciously evaluated. Binding and Tapp (2008 p 123) describe tradition as ‘*cultural, social, and discursive features of our everyday worlds*’. Tradition is what we bring into a conversation or when we are reading a text. It is part of us; we project our thinking from within our tradition, which also

includes our pre understandings that we bring to any event of understanding. It is these pre understandings that inform the questions we ask and to a certain extent what we accept as answers.

Therefore understanding stems from what we have learnt through our professional and personal history, what we are born into and what we learn as we live, through our use of language in textual and conversational settings. This means that the researcher is not completely unaware of the world of the participant. In order to ask the research question, the researcher should already have some understanding of what is sought; hence we have pre understandings or fore-structures of understanding (Geanellos, 1998; Walsh, 1996). Gadamer (1989) argues that it is important to identify the pre understandings and acknowledge them so that they can be taken into account in the act of understanding. An act of understanding occurs when the researcher enters into conversation with participants or reads texts of interviews because the researcher joins in a dialogue with them. This process occurs in a circular motion where the researcher goes from whole to part of conversation, or text and back, to make sense of the whole conversation or text through a cyclic process known as the hermeneutic circle (Debesay, Naden, and Slettebo, 2008).

The hermeneutic circle refers to the idea that an understanding of the text as a whole is established by reference to the individual parts and an understanding of each individual part by reference to the whole. Neither the whole text nor any individual part can be understood without reference to one another, therefore establishing it as a circle. Gadamer (1989) further contributed to the hermeneutic circle by stressing that the meaning of a text must be found within its cultural, historical, and literary context, stating that, within the hermeneutic circle, each person comes to an encounter with pre understandings. As the conversation progresses,

the pre understandings that we begin with are replaced with pre understandings that take into consideration the information we have received, and the meanings that have emerged. In the hermeneutic circle, one does not remain at the same place but moves continually as new knowledge is acquired. As this process occurs continually, the researcher needs to be open to the meaning of the text or the other person and questioning one's own interpretation so as to be open to new interpretations. Gadamer (1989) refers to this as a *fusion of horizons*.

Gadamer (1989) defines horizons as '*the range of vision that includes everything that can be seen from a particular vantage point*' (p.302) which shifts with new understanding. Fusion of horizons is about being open to different standpoints, consequently allowing the standpoints to influence and speak to the researcher or the reader. It does not however mean that the researcher abandons his or her horizon and steps into the horizon of the research participants, rather it is about the researcher placing his or her pre understandings derived from the history of the researcher alongside that of the research participants to illuminate what the participants are trying to say.

A notion of fusion of horizons will be to '*deliberately let into our ontology an awareness of something unexpected... unfamiliar...and to be consciously aware of that differentness.*' (Phillips 2007 p. 91). Hence, the researcher is encouraged to think beyond his or her understanding, allowing for openness that there may be other possible meanings of what the research participants are trying to convey, creating a new horizon in the process whereby understanding is generated. In keeping with this view of openness, the process of interpretation occurs within a circle that is defined by our horizons of understanding.

Hermeneutics describes this process by which insights into human behaviour and our world are interpreted and communicated to the rest of the world. This study aims to follow the tenets of Gadamer's hermeneutics because interpretation within the framework of CTNs seeks to manifest textual meanings rather than individual ones. In engaging within the hermeneutic circle, addressing pre understandings and reflecting their origins and the adequacy and legitimacy of them, allows the researcher to interpret the true meanings of what the participants are saying.

3.3 Study Design

This section outlines the methods used in the study. The selection of the study setting, study participants, ethical considerations, data collection and analysis are discussed and an outline of the criteria by which this work can be judged as rigorous is also presented.

3.3.1 Study Setting

This study was undertaken in the clinical trial centres of two large public teaching hospitals located in metropolitan areas in New South Wales. Three public hospitals were initially approached but the third hospital was not included in the final study because their ethics approval process took longer than expected and sufficient participants were recruited at the other sites to achieve data saturation before ethics approval at the third site was granted. Within the two public hospitals, five different clinical specialties were approached. The study settings were selected based on several factors such as the types and phases of clinical trials conducted at each site, the reputation of each of the study settings and their accessibility to the researcher.

The first factor in site selection was the range of common types of clinical trials research conducted in each setting. For example, both sites conduct treatment trials that test new combinations of drugs or new approaches to surgery; prevention trials that look for better

ways to prevent diseases; or diagnostic trials that are conducted to find better tests for a particular condition. It was also important to seek study settings in which a range of phases of pharmaceutical drug trials were conducted. This was an important factor when selecting the study settings because it indicated that the pool of study participants had a range of clinical trials experience. The study settings chosen for the research study were conducting all three types of clinical trials research as well as various phases (Phase I – IV) drug trials.

The second factor in selecting a site for this study was the reputation of each study setting as a clinical trials centre. This is as an indicator of the quality of clinical trials research conducted at the centre and the calibre of clinical trials personnel involved. A highly regarded clinical trials centre would seek to conduct clinical trials that were reputable, also employing CTNs that were trained and practiced according to good clinical practice (GCP) standards.

The third factor was the accessibility of the study settings. Factors taken into account were facilities that were available for interviews and heads of departments who were willing and interested in facilitating research. In order for the study to proceed smoothly and to gain as much information from the participants as possible, the surroundings have to be comfortable and familiar, and provide adequate privacy to the participants (Minichiello, 1995).

The support and interest of heads of departments was important as they were key facilitators in encouraging and motivating their staff members to participate in the research study and their permission to conduct the study was required. The heads of departments approached were very supportive of the research study and went to great lengths to ensure that appropriate rooms were available for interviews and ensure that clinical trials nurses and principal investigators were informed of the study through weekly departmental meetings.

3.3.2 Study participants

Study participants were recruited from the clinical trial centres of two large public teaching hospitals located in metropolitan areas in New South Wales. These were registered nurses working in the management of clinical trials, and medical practitioners involved in clinical trials as principal investigators. The selection of study participants was purposive as the research study is investigating nurses working in the role of clinical trials research. Therefore nurses working in the role of CTN were approached to participate in the study. Medical practitioners were included in this purposive sample as they worked closely with CTNs and would be able to shed light on the CTN role.

The inclusion criteria for clinical trials nurses (CTNs) recruited to the study were that the participant should be a registered nurse, and working in clinical trials for a minimum period of a year. The inclusion criteria for principal investigators (PIs) included being licensed medical practitioners, working in clinical trials for a minimum of a year and as a principal investigator of at least one clinical trial. The decision to include participants with a minimum of a year's experience was to ensure that they had a sound knowledge of working in clinical trials research.

3.3.3 Recruiting Participants

Recruitment of participants commenced as soon as ethics approval was received from the institutions at which the research and interviews would be conducted. Two strategies were deployed for recruiting participants. One strategy involved recruitment through fliers and advertisements and the second strategy was approaching heads of departments. Fliers were placed in strategic locations such as department notice boards and advertised contact details for the researcher. Two participants (one medical practitioner and one CTN) were recruited using this strategy.

Heads of Departments facilitated access for the recruitment of clinical trials personnel by allowing the researcher to present the research study at weekly clinical meetings the heads of departments also assisted in identifying potential participants who were then approached by the researcher and given information about the study. More than 60 % of the study participants were recruited through these clinical meetings, especially the medical practitioners.

Another avenue for recruitment was through word of mouth, as medical practitioners and nurses were made aware of the study by colleagues. Two of the CTNs were recruited through word of mouth. After speaking with potential participants independently, and assessing their suitability according to the study inclusion and exclusion criteria and gaining verbal consent, individual interviews were organised. This method of recruiting is often referred to as snowballing where potential participants are identified by other participants who share the research characteristics (Schneider, 2007). It is also used when the population under study is difficult to gain access to as it was in this research study.

In total, 19 CTNs and 12 PIs were approached, with 10 in each group consented. Some of the reasons for not participating in the study related to time commitments, not being available during the period of the study, a negative influence from one PI affecting CTNs' decision not to participate in the study and general disinterest in the research. In conducting initial data analysis with the first few interviews, it was noted that interviews could be stopped once there was no further significant data were generated. This is also known as data saturation, where no new or relevant data emerge from the interviews (Schneider, 2007). Therefore recruitment was ended with ten participants in each group when data saturation was achieved.

The ten CTNs consenting to participate in the study were recruited from the specialty areas of Respiratory, Haematology, Hepatology, Neurology and Oncology clinical trials research. These CTNs had worked at an advanced level of nursing for a substantive period of time before transitioning to clinical trials research (Table 3.1). All of the CTNs held postgraduate qualifications in their clinical speciality which ranged from a Graduate Certificate to Graduate Diploma. Eight of the CTNs had held senior nursing roles, before transitioning to clinical trials, two of the CTNs had experience in educating undergraduate nurses within the tertiary education setting and one of the CTNs held a Master in Business Administration. Eight of the CTNs interviewed were responsible in their clinical trial role for one other staff who was working with them. At the time of the interview, all the CTNs had attended courses in Good Clinical Practice and were current with their nursing registration.

Table 3.1: Clinical Trial Nurse Experience

CTN (Pseudonym)	Clinical Nursing Experience (Years)	Clinical Trials Nursing Experience (Years)
Lara	7	9
Mel	13	5
Rina	19	7
Sherry	16	5
Bal	10	2
Ann	14	1.2
Kate	15	5
Sue	20	10
Vicky	6	5
Cris	12	8

The ten medical practitioners consenting to take part in the study were all consultants from the following therapeutic areas: Respiratory, Haematology, Cardiology and Oncology. Five of the principal investigators were professors and held academic positions in universities across New South Wales at the time of the interview, therefore they were not only involved in research at a hospital level but were also recognised national and international leaders in

their area. Three of the medical practitioners were heads of departments at the time of the interview and were involved in decisions about the employment of CTNs. Each of the medical practitioners had been involved in clinical trials for a minimum of two years (Table 3.2).

Table 3.2: Principal Investigators’ Clinical Trial Experience

PI (Pseudonym)	Clinical Trials Experience (Years)
Rob	30
John	20
Megan	3
Jane	4
Jack	10
Ryan	11
Roger	6
Roy	10
David	20
Sam	11

3.3.4 Data collection

Data collection commenced by face-to-face individual interviews as soon as participants provided their consent for the research study. Utilising interviews enables researchers to gain a deeper knowledge of the phenomenon under investigation compared to other methods, such as surveys as they involve social and interpersonal interaction with participants (Gubrium and Holstein, 2001). Semi-structured interviews allow for the broad concept of the study to be guided by the interviewer and be facilitated by devising an interview guide (Polit and Beck, 2006; Minichiello et al. 1999). Semi structured interviews are widely used to seek reliable, comparable data. This style of interview enabled the researcher to ask a mix of open and

closed ended questions and to manage the interview with questions prepared ahead of time. Semi structured interviews also allow persons being interviewed the freedom to express their views in their own terms.

An interview guide was developed to assist as an aide-memoire, to ensure that the key points of the study were covered and to provide clarity. The interview guide was reviewed several times prior to each interview in order to become familiar with the questions and the content that needed to be covered during the interview. Questions focused on the participants' professional backgrounds, transitions to clinical trials research, roles in clinical trials and views of the future direction of clinical trials nurses. The final version of the interview guide is included as Appendix A.

Data collection followed a schedule that was observed closely to ensure that all participants were interviewed within the planned time frame for completion of the research study. Two interviews were scheduled per week and were conducted in one clinical speciality before progressing to the next specialty area. For example, all CTNs and PIs recruited in oncology were interviewed prior to proceeding to haematology. This strategy enabled the researcher to complete analysis in one area and to create more opportunities for seeking a broader range of participants. In short, the researcher was able to use the initial data analysis to shape continuing data collection.

Participants preferred to be interviewed in their work settings, and chose the times for their interviews to suit their working hours. The selection of the interview venue was important; settings chosen by the participants facilitated their ability to relax and open up in the interviews. Participants were offered other venues, such as rooms at the university or their

homes as alternatives to being interviewed at work. Only one participant asked that the interview be held at her home. Interviews were held in conference rooms, in available clinic rooms and in the participants' offices, mostly either early in the morning prior to work, for example at eight am, or during the afternoon, at about two pm.

Time played a big factor in conducting the interviews. All but one of the participants was interviewed at work, which necessitated in the average length of an interview being between 45 minutes and an hour. If the planned scope of the interview was not completed during that time, another appointment was made immediately. Also, it was difficult to arrange interview times with the medical practitioners, as they were committed to various clinics, teaching and surgery. As the interviews in some cases were held a few weeks after the recruitment of participants, some had forgotten that they had agreed to participate in the study and to being interviewed, and the process of reintroducing the study to them and gaining their consent for interviews had to be repeated.

Interviews were all recorded using a readily available analogue audiotape with an omnidirectional microphone. The microphone was very sensitive and ensured that participants did not need to talk loudly for recording, thus creating a more personal and confidential environment. Each interview began with questions on the participant's background and then proceeded to how they became involved in clinical trials. The purpose was to allow the participant to feel comfortable and to open up to further questioning. Questions on background also provided an insight into the participants' personal journey of how they became a CTN or a PI. Following questions focussed on the participants' role in clinical trials, permitting them to elaborate on what they did, how they went about their work and if there were any issues that arose in association with their role. Issues were discussed as these

were raised by the participant, in particular, the participant was encouraged to discuss how these issues were being managed and the challenges they faced in their roles as CTNs or PIs. Inquiry on what the participants thought the future held for CTNs was another topic raised during the interview. Finally, participants were asked if they had any other questions or wished to add anything else to the interview data. Participants were also encouraged to provide as many examples of real life situations and reflect on their own experiences as this added to the richness of the data generated.

After each interview, the tapes were transcribed within 24 hours onto a word processing programme while the information was still fresh in the mind of the researcher. Reflecting on the information gathered during each interview led to modifications to the interview guide as needed and discussion of any issues that arose with the research supervisors, prior to scheduling the next interviews. Transcribing and reflecting on the interview within 24 hours was crucial because, if any problems arose, for example a poor recording or missing data, reviewing field notes could assist in resolution or by contacting the participant to organise a follow up interview. This occurred during three interviews with CTNs where problems were rectified by arranging one follow up interview with each, with no subsequent issues arising. However, if such problems had not been addressed quickly, it may have been difficult to obtain another appointment as participants were often very busy with work commitments. Vital information could have been lost if the problems had been left unresolved.

3.4 Data Analysis

Analysis can occur at various stages of data collection in qualitative research. For the purpose of this study, an initial analysis of data was conducted to ensure that initially, the appropriate cohort of participants was being interviewed and second, that appropriate interview questions were being asked to elicit deep and meaningful information from participants. All interview audiotapes were transcribed by the researcher, allowing the researcher to work closely with

the data and immerse herself in it. Interviews were transcribed verbatim into Microsoft Word, with any identifying information removed during transcription.

Data analysis was conducted within the hermeneutic philosophy framework which is directed towards finding the meaning from the text. Several steps were taken in order to *understand* the interview text. First, the interview text was read by the researcher several times in order to immerse oneself in the text, seeking to achieve a deep familiarity with it, and to acquire a sense of the whole. The text was read with the research question in mind so as to gauge whether the question was being answered. Secondly, headings relevant to the research study were extracted and an interpreted meaning attached to the statement produced. The data were then organised into different themes and sub-themes. These were charted on a large spreadsheet with notes that indicated the locations of quotes in the interview text that provided evidence for the emerging themes. As the analysis continued, the themes were regularly reviewed and occasionally divided and merged. The final action was to reflect the themes back onto the interview text to ensure that the analysis had produced descriptions representative of the research question. This to-ing and fro-ing of the analysis was continuous and circular in motion, in keeping with a hermeneutic circle.

3.5 Rigour and Trustworthiness

It is critical that the rigour of the research method, and its application reflects, the robustness and integrity of the research process is established. For this research study, Sandelowski's (1986) description and discussion of the three criteria for evaluating qualitative research study are applied: these are *credibility, auditability and applicability*.

Credibility addresses the issue of 'fit' between participants' views and the researcher's representation of their views (Schwandt 2001). A study achieves credibility when the reader

is confronted with recognisable experiences from faithful and close descriptions of participants, presented by the researcher. Credibility is confirmed through a number of strategies such as member checks, peer debriefing, prolonged engagement, persistent observation and audit trails (Lincoln 1995). The processes used to enhance credibility in this research study included the researcher presenting faithful interpretations of the CTNs' experience, which other CTNs would recognise as representative of their own. Immediate transcription of the interviews to ensure no loss of information from the interview process was undertaken

The analysis of the data using Gadamer's hermeneutic approach was the second step in ensuring credibility. The key elements of the hermeneutic approach are the hermeneutic circle and the fusion of horizons as discussed and described in earlier sections of this chapter.

Analysis of the data using hermeneutic circle, involves an extended period of reflection of both, *parts* and *whole* of the interview data in order to derive meanings presented. The researcher understands that this process of *toing* and *froing* must come to an end, and holds to an understanding that is presented by the participants at that moment. Simultaneously, the researcher uses her horizons, derived from past and current experiences as a CTN to aid the process of analysis. The researcher, as described in the first chapter, experience as a clinical trials nurse. The researcher's background as an experienced CTN guided the development of the research question and study. The professional background the researcher brought to the study provided an informed examination to explore the role of clinical trials nursing as her experience contributed to her understanding and description of the participants' experience which is consistent with Gadamer's hermeneutic philosophy.

Although the reader may not share the researcher's interpretation, they are able to follow the researchers' steps in analysis and the rationale for the conclusions reached. The process of interpreting and demonstrating that each step in the data collection and analysis is connected to the outcome leads to an audit trail being established. A study's trustworthiness may be established if a reader is able to audit the events, influences and actions of the researcher whilst assuring quality in qualitative studies (Ackerman et al., 2006; Koch 2006; Rice and Ezzy (2005). According to Koch (2006), the audit trail concept stems from the idea of financial audits where independent auditors authenticate a firm's accounts and examine them for the possibility of error or fraud. It is this similar concept and idea that can be used in qualitative research. According to Sandelowski (1986), a study's findings are auditable when another researcher or reader can clearly follow the decision trail and possibly arrive at the same or similar but not conflicting conclusions given the researcher's data, perspective and situation.

In effect, the audit trail provides evidence that the interview text has gone through a process of analysis, reduction and synthesis that can be followed and understood by the reader. This process is transparent in this study because detailed accounts of the design planning, sampling, data collection methods and analysis decisions are presented. An audit trail also helps achieve consistency within the research study.

Applicability refers to the degree to which the findings can be applied to other contexts and settings (Sandelowski, 1986). This research study has been able to establish applicability by providing details of the data analysis and the decisions that led to the findings. The study findings are situated in the participants' current situation and the interpretation is of the researcher's fusion of horizon with participants. By understanding data presented in this

study situated in its present context, a new researcher can make comparisons and therefore transfer these findings to situations and context of their own.

In summary, the findings of this research study reflect implementation of credibility, auditability and applicability of the study thus achieving quality and trustworthiness.

3.6 Ethical considerations

Prior to the commencement of the research, applications to the relevant ethics committees for the three sites were made. An ethics application for Research Involving Humans was approved by the University of Sydney Human Ethics Committee as well as the Human Ethics Committees covering two sites within the Sydney South West Area Health Service (SSWAHS) (now the Sydney Local Health Network).

Informed consent was an important principle adhered to in the study. The study was explained in full to the participants by the researcher to avoid any confusion on the part of the participants and also to provide an opportunity for them to ask any questions relating to the study. As stipulated by the ethics committees, every participant was given a Participant Information Sheet (Appendix B) which outlined the aims and objectives of the study and stated that they were free to withdraw from the study at any time without penalty or prejudice to their work. No participants requested to withdraw from the study. Participants were also required to sign an individual consent form (Appendix C) which outlined in detail what they were agreeing to before the commencement of their interviews.

Participants were made aware that their participation in the research was strictly confidential and only the research supervisors and researcher had access to the study information,

including recordings and any personal references to participants. Permission was obtained from participants for the interviews to be audio taped. All personal details were removed from transcribed materials and from other presentations of the interview data. Pseudonyms were used to identify the study participants as illustrated in Tables 3.1 and 3.2. As requested by the ethics committees, the tapes, journals and all transcripts are stored in a locked facility, accessed only by the researcher, and will remain so for a period of seven years. All tapes will be wiped clean and transcripts shredded after this time.

3.7 Conclusion

This chapter has discussed the methodological underpinnings and the research methods used in this research study. The choice of approach was important in ensuring that the research question was answered and the research aims achieved. Hermeneutics, in particular Gadamerian hermeneutic philosophy was used as an approach to achieve an understanding of the role of registered nurses working in clinical trials research in Australia.

Semi structured interviews with open ended questions were used to seek information from CTN and PIs who were participants of this study. This form of data collection delivered rich and deep data that enabled the researcher to find meaning in the way CTNs and PIs interpret the role that registered nurses play in clinical trials research. The study participants came from a diverse clinical background with many years of clinical experience between them which contributed to the richness of the interview data. Data analysis is described in detail to improve the trustworthiness and quality of the study data presented. Two subthemes and one overarching theme have emerged from the data analysis and will be described in the next chapter.

Chapter 4: Understanding the Clinical Trial Nurse

4.0 Introduction

This chapter presents the findings to the research question posed in Chapter One:

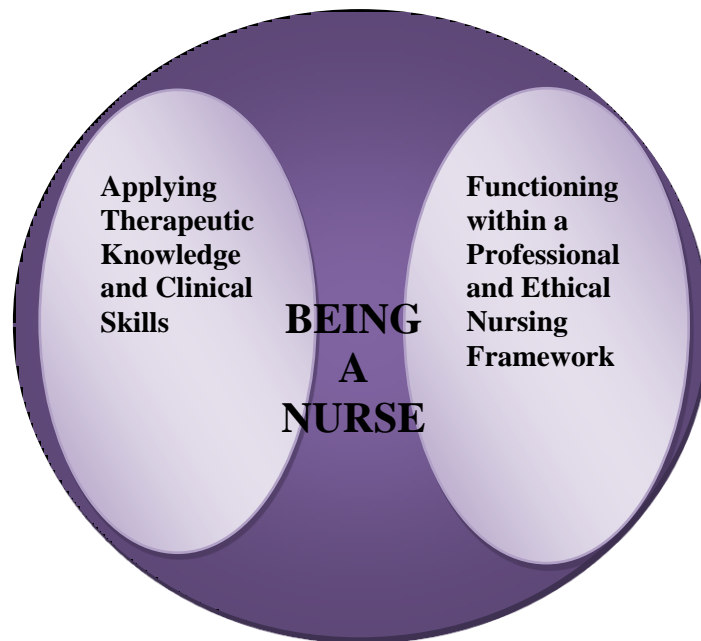
‘What is the role of registered nurses in clinical trials research in Australia?’

The discussion explores the aim of this research which was to examine and describe the role of clinical trials nurses in research in Australia from the perspective of clinical trials nurses themselves and the principal investigators of clinical trials..

Data analysis followed the principles of Gadamerian hermeneutics to facilitate an understanding of the role of the clinical trials nurse (CTN). Data were collected through individual face to face interviews and analysed to identify themes that describe the reality of the role that registered nurses play in the conduct of clinical trials in Australia. The analysis followed a process of categorising meanings from the interview texts, which led to the emergence of an overarching theme of ‘Being a Nurse’ and two subthemes: ‘Functioning from a Professional Nursing Perspective’ and ‘Applying Therapeutic Knowledge and Clinical Skills’.

Figure 4.1 illustrates the themes and how they relate to each other: the subthemes are parts of the overarching theme and the (whole) overarching theme is made up of (parts) the subthemes. The themes are presented as separate components to help understand the whole picture of ‘**Being a Nurse**’.

Figure 4.1: Themes from Analysis of Interview Data



This chapter presents the findings of the hermeneutic qualitative analysis in three parts. The first part presents the overarching theme emerging from the data: Being a Nurse. This theme outlines how the CTNs view themselves as essentially being a nurse in clinical trials research. Both nurses and principal investigators of clinical trials identify that CTNs bring their nursing attributes to their role in clinical trials by virtue of their knowledge, skills and nursing professional backgrounds. Participants identified that the CTNs primarily function as nurses, identify themselves as a nurse, and practice within professional nursing codes of ethics, conduct and guidelines while working in a clinical trial setting. This is further described when exploring the other two key subthemes in part two and three respectively. The overarching theme with its subthemes is supported by exemplars from the interview transcripts in the following sections.

4.1 Being a nurse

Analysis of the interview data identified that nurses working in clinical trials positions, whether titled 'nurse' or 'coordinator', look at this role as a nurse working in a clinical research environment. This framing of their clinical trials role influenced how they undertook many aspects of the research role. It should be noted that some of the CTNs worked from within hospital departments, others conducted clinical trials from a university research unit and sometimes visited wards to recruit or to consult with patients and other health care staff. The analysis of the interview data indicates that because CTNs view themselves primarily as nurses, it influences the way they continue to work in clinical trials research. For example, some of the CTNs would describe their day to day activities from within a nursing framework. For example Sherry, a clinical trials nurse with 16 years of clinical experience described her day to day responsibilities:

'...about explaining stuff to the patient in terms that they understood and using my background really as a nurse to do the follow up work and support as well,...' CTN Sherry

Or the CTNs simply describe themselves as nurses when describing their role as does Rina throughout her interview:

'...the level to which I as a nurse or an intermediary...' CTN Rina

Some of the CTNs would refer to their clinical speciality and how their decision to apply for their current position was influenced by their clinical background, as described by Kate and Vicky:

'My background is in Oncology, Haematology, 15 years of that and when I felt like a change of job and there was a job available in haematology as a clinical trials nurse, so I applied and got it.' CTN Kate.

Of interest, it was also noted that some of the PIs switch between the term *nurse* and clinical trial coordinator, research assistant or clinical trial nurse during the course of the interview. Therefore, although the CTNs are employed under the various formal titles, they were still referred to as a *nurse* by the PIs indicating that the PIs viewed the CTNs first and foremost as nurses. Furthermore, the PIs referred to nursing attributes that helped trial coordinators in the management of clinical trials. Here John, a PI for more than 20 years, indicates how CTNs use nursing strategies and values to enhance patient recruitment:

'...that doctor has a an initial discussion with patient and that is followed by the clinical trials nurse, who maintains sort of a personal interest in the patient and follows through, and that has been a secret of successful trials that we have conducted in this Unit, why our recruitment has been so high.'

PI John.

A need for definition and greater clarity for the role of nurses working in clinical trials research was raised during the interviews. The CTNs reported a lack of recognition of the role within the wider professional nursing circles, and little collegial support. They suggest a national body be established to monitor standards, implement peer review to evaluate their practice and that professional courses be initiated and conducted for nurses who are interested or already in the clinical trial role. They also suggested that the clinical trials nurse role be introduced at an undergraduate level as a valid career pathway for nurses to encourage greater numbers of nurses to undertake this role.

Rina, who has worked as a clinical nurse for more than ten years and oversees CTNs in an oncology unit, stated passionately that as a group, CTNs need to recognise the role as their practice. She explains that if CTNs do not acknowledge and accept their role in clinical trials

nursing as part of their nursing practice, thus not defining the role, issues relating to training and role recognition will continue to arise:

'If you don't have training that addresses the practice role then you need to know what the practice role is. Well that is not defined.' CTN Rina

Rina described how the role of the CTN is often misunderstood by the wider nursing community which gives rise to confusion in regards to titles and between the roles of nurse researcher and nurses in clinical trials research.

'A lot of nurses reject what CTNs do because they don't see it as contributing to professional research... unless you start addressing the nurse researcher and even just defining the fact that nurse researcher is different within your own profession, nothing will change, it will be always be fraught with confusion and so that is part of the problem.' CTN Rina

She further maintained that without definition of clinical trials nursing, the role would remain one without regulation and would continue to present very little to non-existent support for nurses in this role in terms of further education, collegial support and a recognised career pathway:

'Because the nurses are working in a trial...and doesn't have a national body that accredits or has any accrediting type role because they are unregulated then that means you can't address these things in a very easy way in the first instance.' CTN Rina

Sherry and Lara shared ideas similar to Rina's and suggested that a national body be established to ensure standards of practice, educational needs and collegial support for clinical trials nurses are supported, for example:

'I'd like to see clinical trials as a specialty if you like on the New South Wales Nurses Board Registration so that it is recognised as a specialty...as part of the nursing award, like other roles like clinical nurse consultant wound care or diabetes education something like that , so that is what I like to see...larger nursing workforce in clinical trials so like to see some career structure within that.' CTN Lara

To further recognise the role of CTNs and to bring focus to the role as a valid career pathway, it was suggested that nurses at grass root levels be made aware of the role as maintained by Rina,

'...once we start addressing CTN as a professional pathway at undergraduate level and just flag those options as somewhere you can work.'

CTN Rina

The CTNs also described what they foresee as the future for the role of CTNs. Bal predicts that the role is going to get more complex as demands for clinical trials research increases, for example she states:

'funding will impact the way trials are run, there will be pressure on CTNs to enrol patients and as organizations get bigger and larger there will be more demands on the CTN time,...The role will get more technical, more training according to that needs to be established and also more complex in terms of treatment options' CTN Bal

Cris suggests that the complexities would involve increased responsibilities in data management and move towards electronic data capture;

'Buried under a vast pile of paperwork, where it is going? Look it is all going to be shifting to electronic, we have already started 'CTN Cris

Many of the CTNs referred to the need to enable progress and expansion of baseline knowledge and skills in clinical trials research, training in regulatory affairs and gaining informed consent, and the need to gain an understanding of the whole clinical trials research industry and communication skills. Cris, who has varying levels of experienced CTNs reporting to her suggested:

'Education, clinical trials, I guess it depends on what their base line knowledge level is... they really need to know about an overview of the whole process not just their particular study but the whole process of the industry needing to look at these questions and the process of getting drugs to the market place and the process of getting the ethics committee approval and the process of recruiting the patient...' CTN Cris

All of the CTNs mentioned some form of training for both novices and experienced CTNs. However, a few of the CTNs mentioned the need for a formal postgraduate course to enable a career pathway for the role. The courses available at the time of the interviews were mainly sponsored by the clinical trials research industry, for example one of the CTNs suggested:

'...postgraduate course would be a great thing, I think that is where it will end up.... I think there needs to be a postgraduate course in it...' CTN Vicky

The participants were confident that the clinical trials nursing role is here to stay. Participants clearly identified a need to establish a national body that will help regulate, provide collegial support and grow this role within the wider nursing body. The aspects that the CTN

participants have mentioned in regards to continued training and the future consolidation of the role apply to functioning as a profession and contributing to their professional role as a nurse.

In analysing the data, it is clear that the CTNs have raised points related to 'Being a Nurse'. The CTNs describe their role as utilising their knowledge and skills from their nursing background and clinical speciality. The CTNs describe their experiences in their current role with some amount of frustration especially when discussing issues such as collegial support, role identification and education leading to career pathway. These issues are also reflection of professional nursing practice which identifies the CTNs as 'Being a Nurse'

The analysis of the interviews highlights that CTNs utilise their nursing skills, knowledge, values, and expertise in their role in clinical trials research. In utilising their nursing background, the CTNs have demonstrated critical thinking and implementation of the nursing process in their roles. Nursing process is an integral part of nursing practice as it provides a framework and foundation for their practice which the CTNs have indicated throughout the interview. They describe their role in terms of being able to assess, analyse, plan, implement and evaluate situations as it arises. Thus providing leadership in the conduct of clinical trials and enhancing study integrity.

These concepts are further expanded in the identification of the two subthemes Functioning within Professional and Ethical Nursing Framework and Applying Therapeutic Knowledge and Clinical Skills. These themes are significant because they contribute and expand the picture of being a Nurse, providing further understanding to the role that CTNs play in clinical trials research.

4.1.1 Functioning within a professional and ethical nursing framework

The subtheme *functioning within a professional and ethical nursing framework* articulates how the CTNs enact their role, informed by their nursing knowledge and expertise underpinned by their nursing professionalism. The analysis of the interview text illustrates how the CTNs function from within a professional nursing framework which is guided by the Codes of ethical standards and practice that is both formally and informally a part of the nursing profession. This was evident in three ways: the CTNs management of ethics and regulatory affairs, their engagement with the consent process and their handling of research data.

The ethics process for clinical trials is rigorous and detailed, as described in Chapter Two. As for all clinical research, clinical trials ethics applications require preparing documents such as consent forms and patient information sheets, liaising with ethics committees and assuming responsibility for follow up for the ethics submissions and reports as required by the ethics committee. All participants in this study identified ethics submission as part of the CTNs' role in coordinating clinical trials research.

'I draw up all the relevant documents including ethics submission, which includes the clinical information and participation information sheets.' CTN

Lara

In preparing these documents, the CTNs identified that they require knowledge and ability to implement and monitor the study according to international standards for good clinical trials research practice and an in depth understanding of the study protocol. Some of the CTNs recognised that it was an area that required formal training which needed to be addressed. Others CTNs delved into their professional background of nursing and clinical expertise to understand the intricacies of a study protocol.

Following ethics submission, recruitment of patients into a study was identified by the CTNs as the next most important part of their role in clinical trials research. A key factor of the recruitment process that involves CTNs is their engagement with the consent process. The analysis of the interview data indicates that CTNs demonstrate professional nursing skills and leadership qualities in ensuring patient comprehension and safety during initial and ongoing clinical trial informed consent decisions. CTNs achieve this by going beyond simply providing information to the patients as they took their time to walk a potential trial participant through the clinical trial process and communicating all aspects of the trial to the patient and their family or carer.

Concurrently the CTNs performed a detailed assessment of all aspects of the patients' medical and psychosocial history in order to ensure that the patient was not only meeting clinical trial criteria, but was also able to participate and understand clinical trial requirements. This process of checking and ensuring that patients and their family are fully aware of their commitments is reflective of nursing practice whereby, nurses ensure that patient safety and comfort is maintained at all times.

Communication skills were a key element of the informed consent process; while communication appears to be important in all aspects of the CTN role, it will be explored in detail in the discussion of the **applying therapeutic knowledge and clinical skills** subtheme.

All participants outlined a detailed understanding of the informed consent process, describing elements of the process with reference to what it is, the assessment of patient understanding and knowledge, and who is responsible for gaining consent. There were mixed views from

PIs regarding the role of CTNs in obtaining consent. Four PIs stressed that it was ultimately the responsibility of the PI to gain consent from the patient as described by Ryan below,

'No, I think that they [obtaining consent] should always be performed by a physician because informing people about side effects, I guess is an important part of consent and having seen side effects or treating people who have undergone complications because of drugs, I think that it is an important component to being able to provide consent and only a passing or only a theoretical awareness of side effects that are rare but catastrophic,...' PI Ryan

The other six PIs had no problems with CTNs obtaining consent provided that the trial protocol did not require a PI to gain consent as indicated by Roger,

'in some studies I may consent the patient for the study, in others I may have a supervisory role where a nurse or an associated fellow consents the patient... It would depend on the requirement of the study and the expertise of the people who are around...' PI Roger.

These six PIs described trust and confidence in the CTNs' clinical knowledge as well their understanding of the clinical trial protocol as described by John,

'Yes absolutely, provided that they were appropriately trained and sensitive and you know all the things that good clinical trial nurses need to be.' PI John

Of note, the CTNs stated that it was ultimately the PIs responsibility to gain consent from patients due to protocol needs, however two CTNs highlighted that they had a role in the process of obtaining consent, for example:

'I feel that it is not so much the doctor explains that fully to the patient so I feel comfortable obtaining consent from the patient in the screening phase because I explain it very well to them, what it involves, the risks and the advantages and the benefits.' CTN Ann.

Both groups of participants regarded the consent process as critical to the role of the CTN.. The analyses of the transcripts indicate that CTNs utilise their communication skills to help the patient and their family navigate through the informed consent process. The PIs identified that CTNs spent additional time with potential study participants in clarifying all aspects of the study therefore facilitating patients in their decision making process for consent, and acting as a liaison between the PI and the patient, described by one PI as:

'So the trials nurse, I see it as a different person to help the family, patient's family to understand the clinical trial and the context of the trial.' PI Jade

The CTNs highlighted that the requirement for informed consent is not merely met by completing a signed informed consent form: it is a process that requires participation from them and the patient as well as their family or carer. Steps in the process include taking the time to outline information to the patient so that the patient and family are fully informed and know what their responsibilities are to the clinical trial, for example:

'..Really important, because obviously, people couldn't make a decision on one appointment and it was very, very important that they have a person that supports and explains what the trial is about and repeatedly do this and be available for them to understand before the person could then make an informed decision..' CTN Sherry

Similar thoughts were expressed by other CTNs in this study who were very passionate about how and in what context information about the trial was delivered to the patient. Analyses of the transcripts reveal that CTNs endeavour to maintain honesty in their information transfer and allow for clarification of all issues that would impact upon the patient as a person.. In this way, they are counselling participants on what to expect during their participation in the trial, as evidenced by the exemplars below:

'I think I'm more honest. The head and neck (cancer patients) especially, I sit down and take time [with] them. The treatment is horrific. I don't think anyone says that to them but I actually say to them, "You have a really difficult road ahead of you and mentally you have to prepare for that." And I think that is important and I don't think anyone says that and I have never ever heard a doctor say that to them. It is assumed...' CTN Bal

'...I just don't think that they [PI] tell patients the full extent, the possible side effects or outcomes from what they [patients] consent to, just from getting patient feedback, when they get sentinel node biopsy surgery and wide excisions, you ring them up a week later and they say, "I am in so much pain, the doctor did not tell me that I will be in so much pain." And that has come through quite a lot and the doctor has told them, "Oh! You will be sore for a couple of days and you will be right as rain." Or "You will back at work in 2 days." It is a week later and the patient is still taking Panadeine. I think that had definitely come through, that they are not given, things are skimmed over like or I mean we are all health workers things become routine but for the patients it is not routine, it is a big thing and I think doctors could be

dismissive, not all of course, but they can be dismissive of what it actually entails.’ CTN Ann

Another important factor to emerge from the analysis of the interview text is the recognition of the vulnerability in patients by the CTNs. Some of the CTNs expressed concern in regards to patients’ emotional and mental status when discussing clinical trials study participation.

Mel reports that patients were often traumatised when they hear their diagnosis of cancer, therefore are not able to absorb and digest information in regards to clinical trials participation,

‘They have had very traumatic news, they are anxious, all those things that come with having a diagnosis of malignancy. So when patients ask me things and I think you should have heard this, you should have been discussing this fifteen minutes ago when you were in whoever’s office. I also have to factor in that they may have and they may just not have absorbed it.’ CTN Mel.

She further describes how she feels conflicted that the responsibility becomes hers to ensure that the patient receives the right information,

‘Generally my main concern is that I do feel the weight of the responsibility of conveying the accurate and the correct information to them and I do not think it is my sole responsibility. I know it is not my sole responsibility to do so. I guess sometimes I think I would like to have some reassurance that it is also coming from the medical side.’ CTN Mel

The analyses of the interview text indicates that CTNs face many challenges in regards to disclosure and the quality of information transferred and how this impacts upon the safety

and comfort of the patient. CTNs reported that they were able to make a judgment and take appropriate actions to ensure the safety and comfort of the patient using their nursing skills of assessment. CTNs stated that they endeavoured to be present when the patient is first introduced to the idea of clinical trials in order to gauge a patient's understanding and assess their emotional status from the outset. They also spend an extended time with the patient and their family discussing the trial and being available to them for questions and importantly arranging further consults with PIs as soon as possible for clarification and signature of consent forms.

'I think that the only thing we can do is to act as that go between and talk to the patient and make sure that if they do have any questions, to write them down and that the doctor is there for them, they are not to feel that they are being rushed and that, you know, they have to take the time to, you know have their questions answered...' CTN Ann

The analysis of the interviews identified other challenges relating to patients' rights in clinical trial research. For example, Cris found herself in a situation where the patient's ability to consent was compromised:

'..... there was a patient who has an intellectual disability...some recent health drug issues as well and I was not certain about his intellectual capacity to digest that nine pages of information and to make that decision so I brought his case to... we have a regular weekly meeting with our psychiatrist and our team and ask their opinion, you know, discussed him in detail and got them to have a look at him and to assess his ability to give legal consent.' CTN Cris

In other cases, however, the CTNs do not involve others to resolve ethical dilemmas. While CTNs acknowledge the value of clinical trials research for the advancement medical knowledge and the development of new and effective therapies, they expressed their primary obligations to ensure the safety and welfare of individual patients in their care. An example of this is when patients ask for a nurse's opinion about a trial. CTNs maintained that their role was to facilitate the patient's choice to enter a clinical trial without any bias or coercion. For example, Rina related a patient discussion:

[The patient asks] *"What will Professor K do if I don't go on this study."*
"Absolutely nothing".... and the nurse, in our role we are providing the space for them to make that decision.' CTN Rina

While CTNs understand that there are regulatory requirements governing clinical trials research, they appear to be influenced more strongly by the ethical frameworks of the nursing profession rather than the research frameworks of the clinical trial. . John, one of the PIs gave an example where the CTN did not want to recruit a patient because there was a language barrier on the patient's part, he stated:

'...one of our CTNs was not comfortable that the patient's English was good enough to understand, I thought it was and she felt it wasn't, so we are getting a third opinion...[laughs]...and talking to the relatives who weren't present at that time...it hadn't occurred to me that she had any particular difficulty with English, she thought that.' PI John

The CTN insisted that they obtain another opinion and speak to the patient's relatives before deciding to recruit the patient into the clinical trial.

Although the PIs maintain that allowing for another objective view on the consent process is good practice, not all of them agree who has ultimate responsibility for refusing a patient entry onto a trial. I Megan states for example that the final decision should be taken by the PI:

'...it is not their role [CTN] to say, "I think that you should stop this trial on this patient because of this and this..." I mean they may and I guess the clinician has to take that in consideration but I don't think it is actually their role to say, "I think you should stop it on this patient." I think that their role is to present all the information saying, "This is all the complication this patient has had, this is how bad it is, what you want to do?" It is an approach rather than single handed say, "This is what I think is for the patient." PI Megan.

The analysis of the transcripts illustrate that the clinical and assessment skills of CTNs are important for demonstrating knowledge of each designated clinical trial protocol, including the procedures and documentation necessary to ensure the safe and accurate conduct and recording of data and study outcomes:.

'..advanced skills that the nurses have...also means that the follow up in the data collected is much truer to the outcomes of the study, which is extremely important when you are talking about the ethical nature of human research.'

CTN Rina

The CTNs ensure that data is recorded accurately and in accordance with regulatory requirements by adhering to guidelines and study specific documentation. This reflects the CTNs' understanding of the clinical implications of accurate recording and management of data which is drawn from their nursing standards of practice. CTNs engaged in the collection

of clinical trials data obtain and validate clinical results, for example pathology related to the particular clinical trials study, and sometimes handle tumour tissues or pathology slides:

'is a lot of paper work, keeping up to date on patient records, entering details into patient's database, doing electronic CRF [Case Report Form enables collection of data in a consistent manner, available both in paper and web base] entry, de identifying pathology slides and sending them to the USA and also reporting adverse events.' CTN Ann

The analysis of the interview text exemplifies how CTNs function from within a professional nursing framework guided by the ethical standards and practices of the profession to maintain integrity and confidentiality in the process of data collection and management.

In summary, it appears that both CTNs and PIs participating in this study agree that essential criteria for the CTN role include helping to identify potential patients for studies, recognising those who may not be able to give informed consent or complete a study for reasons that might not be evident in the protocol, ensuring that the patient and their important family members are included in decisions, that all aspects of the participation in the study are clear during the consent process, that data collection and management of the conduct of the study is maintained within ethical frameworks and guidelines. This is an area where the CTNs' professional knowledge and skills as a nurse came to the fore. CTNs can assess patients for entry to clinical trials using their professional nursing skills which are underpinned by ethical, legal and moral obligation to the patient to ensure that patients' rights and welfare are protected, essentially practicing from within their professional nursing framework and Codes of Ethics and Professional Conduct as outlined by the Australian Nursing and Midwifery Council.

The next section will explore the theme of therapeutic knowledge and clinical skills in clinical trials practice. The exploration of this theme reveals how CTNs further enact their role within a nursing framework.

4.1.2 Applying therapeutic knowledge and clinical skills

Analysis of the interviews revealed how CTNs draw on their nursing skills and knowledge to practice as a CTN. While not a surprising finding, the degree to which the nurses functioned as a nurse working in clinical trials, rather than a clinical trials nurse, was greater than anticipated. Each of the CTNs participating in this study worked in a research role that required interaction with patients. All participants worked on medical-led trials where a drug or surgical intervention was being investigated.

None of the CTNs participating in this study had responsibility for the provision of direct patient care for the study participants. Yet across all CTNs in this study there was evidence of interaction with clinical trials participants in a therapeutic nursing relationship. These were not components of the trial protocol. While some trials required the CTNs to use their nursing skills, for example venepuncture and physical assessment, both participant groups identified the nursing knowledge and understanding CTNs brought to clinical trials as a factor related to the success of the trials.

The nursing knowledge reported as making a significant contribution to clinical trials by the CTNs includes disease and treatment knowledge in both general and particular clinical specialties. Clinical skills that the participants describe as contributing to the success of the trial comprise of nursing clinical skills, for example phlebotomy, medication administration, interpreting test results and equipment handling. Both groups of participants in this study report that the CTNs utilise their nursing knowledge and clinical skills in critical thinking and

decision making, facilitating and maintaining relationships with patients and PIs, and in their assessment of patients' suitability for clinical trials research.

One of the key sub-themes to emerge from the interview text was the value of the communication skills of the CTNs. These were highlighted by both the PIs and the CTNs. Analysis of the interviews demonstrates that CTNs have superior communication skills which have developed during their nursing backgrounds and which they utilise in clinical trials settings. The communication skills of the CTNs were described as an all-encompassing factor in the management and coordination of clinical trials research. Participants of this study described the communication skills of CTNs in terms of establishing a good relationship between patients, PIs and CTNs, establishing a working relationship with other health care professionals and departments as required, maintaining relationships with patients and colleagues throughout course of clinical trials and using their interpersonal skills to manage clinical trials as a whole.

Participants described that CTNs facilitated lines of communications that intertwined throughout the whole clinical trials research process:

'...one of their major roles is just, organising the whole process, important role is communication throughout the whole, that period of time when the patient is enrolled and identifying any problems that the patient has as a result of being on the trial, that is important.' PI David

As the exemplar above indicates, communication occurs from the initiation of the clinical trials and follows through with recruitment of patients and managing patients throughout the whole clinical trial. In recruiting and managing patients on clinical trials, both groups of participants stressed the importance of communication skills and the PIs in particular relied

upon the CTNs to maintain relationships with patients and facilitating the PI and patient relationship. Analysis of the interviews indicates that CTNs act as an intermediary between the patient and PI by being proactive in anticipating issues and ensuring that protocols and procedures are met:

'they [CTNs] have a big impact, in bringing the patient and doctor closer together,....communicating any potential problems to the patient and also encouraging the patient to communicate more with the doctors.' PI David

'...they [the CTN] come to me with any problem and are excellent at communicating with the patient and myself so that they are very on the ball and in some cases remind me to do certain things that I forgot to do! [Laughs] ... which is great and it actually makes me feel much more comfortable about running the trial because I know that they are on top of things.' PI Megan

CTNs have already learnt to work collaboratively with multidisciplinary teams in the clinical setting from their nursing experience. Participants in this study reported that CTNs maintained lines of communication with a wide range of people during the set up and conduct of clinical trials. Apart from the clinical trial research team, CTNs described that they liaise with hospital personnel such as radiology and laboratory staff, with ethics committees, clinical trial sponsors and trial monitors.

Analysis of the transcripts also illustrates that the open dialogue between patients and CTNs creates an environment for integrated care throughout the clinical trial process, as described by Mel:

'...nothing happens in a trial unless you have effective communication between trial staff and your patients and better that communication role in those relationships are... the better your running of the trial is, your data is cleaner, your recording is better, your compliance with the trial procedures is better, patients are happier with their trial participation and their general care.' CTN Mel

The interviews highlight that CTNs establish rapport with patients and develop a trusting relationship by listening, being responsive to patient's needs, portraying an interest in the patient, clarifying information in a manner that the patient understands and providing information when consulting with patient. Mel describes how listening skills are important, especially in the context of gaining consent. She presents here as an active listener, interested in what the patient has to say without making any judgements and providing them time to make their decision.

'Listening is very important, patients need to feel that they can talk things through,... a matter of just listening what they are considering, therefore the consent process is easier and they come to that decision in their own time.'

CTN Mel

This is not very different to the clinical setting where nurses establish relationships with their patients in order to know them better in order to provide more effective care for them. This suggests that patients may feel more comfortable discussing issues with CTNs rather than their doctors or PIs of clinical trials:

'... you are spending more time with them so you get to know them better and you build a bit of a rapport and sometimes they would tell you things that they wouldn't tell the doctor' CTN Vicky

CTNs report that at these initial stages of building relationships with trial participants, skills such as listening and being attuned to patients' needs are important as they can lead to positive outcomes as described by Ann who coordinates an international multicenter clinical trial study:

'Because nurses tend to have good communication skills and talk to people and I mean that is something that we got back from, with the trial after 12 months, the monitors came out and we are doing well at our site because we [CTNs] can talk to people, we've got good people skills and people can relate to us.' CTN Ann

The interview data in this study suggests that CTNs apply their therapeutic knowledge base and cognitive, critical thinking and decision making skills to supporting patients through their clinical trial journey.. Both groups of participants in this study maintained that CTNs utilise their clinical skills to assess a situation, tune-in to the needs of the patient and help and support the patient as need arises. CTNs use the knowledge obtained from forming therapeutic relationships with their patients to develop and implement strategies related to patients' health and welfare, such as informing them on matters related to their clinical status. A common pattern to emerge from the interview data was where CTNs view the patients' care as more than that required or mandated within the clinical trials setting:

'someone was having quite a lot of symptoms that weren't so obvious when they came to appointments, you might say well then, bring the palliative care team in or there is somebody who is older, decrepit or fatigued, you could do something like get high seated toilet, just meet their occupational therapist and that type of thing, make their circumstance a bit better in the process.'
CTN Sherry

'..and the understanding of the disease process and a medical/nursing understanding helps also in terms of trial work, things aren't cut and dry, things aren't concrete for patients and the information that they get is often vague and non specific and they are dealing with a lot of uncertainty..' CTN Mel.

Together with their knowledge of the healthcare system, hospital policies and procedures and the workings of interdisciplinary care, CTNs effectively manage the needs of trial patients as supported by the exemplars below:

'..those advanced skills that the nurses have... understanding the disease process, being able to do those assessments and refer appropriately means that you are actually getting your patients to stay on the study.' CTN Rina

'You are one of usually a number of health consultants that they are seeing [the patient] at the same time, so they have their GP, so you would coordinate from the point of view of the study.... refer them to someone more appropriate' CTN Vicky

The CTNs claimed that it was not only their experience in the clinical trial speciality that was helpful, as their general nursing and other clinical speciality training became useful when dealing with patients on clinical trials as exemplified by Sue:

'...you need nursing knowledge to actually do clinic work for a number of trials, for in MS you can say well what do you need, neurology or whatever, well I have cardiothoracic background and I cannot tell you how handy that is, I mean I use it non stop and it is to the advantage of the trial really, we do pulmonary function tests, chest X-Rays, we do ECGs, you know I can look at those and I know instantly if there is a problem...' CTN Sue

The PIs also identified this aspect of the CTN role as important. The PIs stated that the ability of CTNs to identify medical problems, understand disease processes and the treatment under investigation were invaluable qualifications and background for the role of clinical trial coordinator:

'I think a nursing background, because just going back to the point of them needing to have some clinical, nursing background looking after patients before...Nursing background is also good because people tell you about medications and you should be able to understand what they are talking about.' PI Jane

Analysis of the interview data obtained for this study highlights that CTNs utilise their critical decision making skills, evaluating the patient's history and personal situation before consulting with them regarding their final decision on trial participation. CTNs indicated that recruiting patients into clinical trials required more than just meeting clinical trials criteria and protocols; there are psychosocial and physical needs of the patients that also should be addressed. In performing their clinical assessment, CTNs are working from within their nursing framework which is also about a duty of care to the patient as described below:

'a patient, he was encouraged to go on the study, I went up to see him... talked to him for a while, he was really keen to go on the study, older gentlemen...he was also his wife's carer, just wasn't practical for him to give us the time that I was asking of him, so in that case, I am more than happy to say, "Look we would loved to have you on the study but in your situation, I understand that you are the carer for your wife and time is an issue." He agreed.' CTN Bal

Within the **therapeutic knowledge and clinical skills** subtheme, the participants of this study have described and highlighted how their nursing therapeutic knowledge and clinical skills is utilised in their clinical trials role. The CTNs describe how they utilise their extensive nursing background to assist in decision making in regards to patient care and their safety.

The analysis of the transcripts illustrates that CTNs facilitate and maintain relationships between patients and PIs by establishing a rapport with patients to create a supportive and trusting environment for the patients throughout their clinical trials journey. This aspect of their role, together with fulfilling CTN tasks within a professional and ethical nursing framework, contributes to the understanding of the CTN role as 'being a nurse'.

4.2 Conclusion

It is evident from the analysis of the interview data that the CTNs practice within a nursing framework. The CTNs describe their clinical trials practice from within a professional nursing domain. These descriptions include autonomous practice and advanced negotiating, communication, interpersonal and leadership skills. The CTNs accomplish this by drawing upon their professional nursing and ethical background. The analyses of the transcripts indicate that CTNs utilise aspects of the nursing process to assess, implement and evaluate their decisions in relation to gauging a patients' understanding of clinical trial requirements and the clinical trials journey. This is reflective of functioning from within a professional and ethical nursing framework.

The second subtheme further illustrates how the CTNs are 'Being a Nurse'. The CTNs clearly describe and explain how they use their therapeutic knowledge and clinical skills to integrate into the clinical trial coordinator role. The CTNs indicate that they apply their therapeutic knowledge and clinical skills to assist the patient in making their trial journey as comfortable as possible. The CTNs point out that they are able to do so because they bring forth their extensive nursing background to help patients understand the intricacies of trial

requirement by listening, helping patients understand the disease process, caring for their multitude of social and health problems and being able to refer them on appropriately within the health system. In creating this safe and comfortable environment, the CTNs form lasting relationships with their patients and the clinical trials team, which in turn as stated by the CTNs ensures good participation leading to good outcomes for any clinical trials.

In conclusion, the CTNs have demonstrated through the two subthemes that they are, 'Being a Nurse'.

Chapter 5: Discussion

5.0 Introduction

The aim of this research study was to investigate the role of clinical trials nurses (CTN) in Australia. The research question: ‘What is the role of registered nurses in clinical trials research in Australia?’ was explored using a Gadamerian hermeneutic approach. Through the analysis and interpretation process, themes emerged from the interview data, forming a comprehensive picture of the CTN experiences and understanding of their role in clinical trials research. This chapter discusses the themes that emerged from this study in relation to current and past research and relevant scholarly literature where available.

One overarching theme ‘Being a Nurse’ and two subthemes: ‘Functioning from a Professional and Ethical Nursing Perspective’ and ‘Therapeutic Knowledge and Clinical Skills’ emerged from the analysis of the interview transcripts. *Being a Nurse* explores how the CTNs view themselves and how PIs view the CTNs in their clinical trials role, specifically the utilisation of their knowledge, skills and professional nursing background. This theme also encompasses the challenges faced by CTNs in an ambiguously defined role that they still considered to be a nursing role, yet lacks a clear career pathway. This major theme is further expanded by the two subthemes.

The first subtheme, *Functioning from a Professional and Ethical Nursing Perspective*, describes CTNs working from within a professional nursing framework underpinned by ethical practices as guided by the Australian Code of Ethics for Nurses which provides a framework for accountable and responsible nursing practice (Code of Ethics for Nurses in Australia, 2005). The second subtheme, *Applying Therapeutic Knowledge and Clinical Skills*, describes how CTNs draw upon their clinical knowledge of assessment, planning and

evaluation in clinical trials research coordination and management, and employ a range of interpersonal skills to facilitate relationships between patients and the clinical trials research team. The themes found through the analysis of interviews in this study cannot be considered individually or in isolation, but together to provide a picture of how CTNs and Principal Investigators (PIs) of trials interpret the role of the registered nurse in clinical trials research.

5.1 Being a Nurse

The findings of this study demonstrate that both CTNs and PIs view CTNs as nurses working in a clinical research role, with their professional identity, knowledge and skills as nurses being central to the CTN role. Throughout the interviews conducted in this research study, the CTNs identified themselves as nurses and not as researchers. Furthermore, the CTNs often described their nursing colleagues conducting clinical trials research as '*the nurse*' or '*nurses*'. PIs likewise referred to the CTNs as '*nurses*' when describing the roles and responsibilities of the CTNs, at times addressing CTNs as clinical nurse consultants or clinical nurse specialist. This reiterates the notion that the PIs see the CTNs in a specific professional light and recognise them first and foremost as nurses.

Fagermoen (1997) refers to professional identity as the nurse's conception of what it means to be and act as a nurse and how a nurse's philosophy of nursing is represented. By consciously reaffirming their professional identity, the CTNs appear to hold a connection to everyday nursing practice and this identity was evident in the examples the CTNs and PIs provided in the course of the interviews. Hence, this professional identity as an expression of the values and beliefs held by the CTNs, guide their thinking and actions within their role.

In addition to retaining a professional identity as a nurse, CTNs also appeared to value their nursing background and experiences and realise their applications in a clinical research

setting. For example, the CTNs would constantly refer to how their nursing background and experiences supported their decision making process in clinical trials management, facilitated relationships between themselves, patients and PIs, and helped overcome situations or challenges encountered in their CTN role. These references were echoed in the PI interviews, where the PIs indicated that someone from a professional nursing background provided research teams with an in-depth knowledge base and cognitive, critical-thinking, and decision-making skills that was beneficial to their research.

The attributes that the PIs refer to are reflected in the nursing competency standards and practices that are outlined by nursing bodies around the world. The Australian Nursing and Midwifery Council (ANMC), the peak national body for nurses and midwives in Australia, has set national standards for the educational preparation of nurses since the early 1990s (ANMC, 2006). These standards are presented as domains which all nurses in Australia are required to demonstrate in order to practice as registered nurses. These domains are professional practice, critical thinking and analysis, provision and coordination of care and collaborative and therapeutic practice (ANMC, 2006).

Professional nursing practice can be described as having a patient-centered focus, being accountable for practice, and making sound judgements based on experience and knowledge thus acting within the legislative framework of nursing and health care (ANMC 2006; Girard, Linton & Besner 2005). The CTNs in this study discussed how they coordinated trial patient care by utilising their clinical experience and knowledge to make clinical and non-clinical judgements. For example, the CTNs were able to review and interpret pathology results and electrocardiogram (ECG) and alert PIs to any abnormal results. The CTNs further discussed how they collaborate with other departments in coordinating patient care based on their

professional knowledge, for example utilising social workers, diabetes educator and community nurses.

They also described being accountable for their own practice while acting within the scientific, legislative and ethical requirements of clinical trials research. It was highlighted during the interviews and in the literature review (Chapter 2) that the successful conduct of trials hinges upon vigilant implementation of regulatory aspects and clinical protocol (Nagel 2010; Catania et al., 2008; Rickard et al., 2006). Drawing upon their experience in diverse clinical settings and backgrounds, the CTNs were able to autonomously make decisions in clinical care of the patients. The CTNs were constantly aware of their accountability when making decisions thus acting within the needs of clinical trial protocol as well as good clinical practice. However, there were times that the CTNs felt that the clinical trial protocol did not suit the patients and raised this issue with the PIs for example treatment regime and the overall benefit to the patient. In addition the CTNs utilised their professional knowledge and experience to provide clinical and emotional support and education to patients and staff involved in the trial process (Bell 2009; Bird and Kirschbaum 2005).

The CTNs also outlined the need for more education in aspects of their role, particularly those involving regulatory aspects which their clinical nursing background did not prepare them for. Suggestions presented by the CTNs included provision of training and education for research skills and preparing a clear career pathway to clinical trials nursing which included a set of national competencies similar to those developed for other nursing specialties such as cancer or palliative care nursing.

The domain of critical thinking and analysis within the Australian competency standards relates to '*self-appraisal, professional development and the value of evidence and research for practice*' (ANMC p2, 2006). Within this domain, the registered nurse is able to continue

developing their current knowledge base, share it with other health professionals and nursing colleagues and provide critical thinking in decision-making (ANMC 2006; Girard, Linton & Besner 2005). The CTNs in this research study demonstrated how they utilised critical thinking in their decision-making process in terms of coordination of care of the patient which included the ability to use evidence gathered through both professional and personal experience. Provision and coordination of care defines the ability of the registered nurse to coordinate, organise and provide nursing care that includes the assessment of individuals and or groups, planning, implementation and evaluation of care (ANMC, 2006). The nurses in this study defined their role in terms of being responsible for assessing eligible patients for the trial, enrolling, obtaining informed consent, administering and monitoring study treatment and the progress of patients, as well as being involved in patient education and overall coordination of care of patients whilst in clinical trials.

Similar to competencies required for critical thinking and analysis, the provision and coordination of care domain also involves the CTNs engagement in creative problem solving as well as evaluating and questioning outcomes and inconsistencies. Both CTNs and PIs described situations where CTNs actively questioned patient eligibility and challenged the validity of placing certain patients on clinical trials. The CTNs worked within an appropriate ethical framework and used clinical judgement and decision-making skills to coordinate and manage challenges in their role as encountered.

Collaborative and therapeutic practice refers to *'establishing, sustaining and concluding professional relationships with individuals and or groups'* (ANMC p2, 2006). CTNs in the study referred to the importance of having confidence in their ability and taking responsibility for their actions, including having a comprehensive understanding of the professional boundaries and limitations of nursing practice. On the other hand, the CTNs in this study

described that their practice can only grow with collegial support (which they currently saw as lacking in Australia). The CTNs revealed that at times, their role was not acknowledged as a nursing role, particularly by nursing colleagues and Australian nursing bodies themselves. This in itself leads to a dilemma of where CTNs stand in the professional practice of nursing as there is no national recognition of their role in nursing legislation, therefore no set guidelines for their specialist practice and no avenue for the CTNs to discuss and solve professional practice issues they see as specific to their role.

Eaton and Pratt (1990, p 138) state empathetically that nurses employed in the role of trial coordination 'play the pivotal role in the daily conduct of a clinical trial'. The authors, (medical practitioners) describe further how they recruited nurses from specialist clinical backgrounds, and provided training to fulfil trial coordinator positions, suggesting that this route would lead to more successful trial conduct. Thus, the overarching theme of *Being a Nurse* found in this study demonstrates that CTNs utilise their nursing skills and expertise to positively contribute to clinical trials research, which is recognised and seen as beneficial by both CTNs and PIs.

In the following sections, further understanding of the role that CTNs play in clinical trials research, will be discussed through the two subthemes which contribute and expand the overarching theme of *Being a Nurse*.

5.1.1 Functioning from a Professional and Ethical Nursing Perspective

The subtheme comprises the description of the CTN role from a professional and ethical nursing perspective. As noted in Chapter 4, this was evident in three areas: 1) managing ethics and regulatory affairs, 2) involvement in the informed consent process, and 3) handling of research data. As indicated in Chapter 4, involvement in the informed consent process

sometimes raised ethical dilemmas for CTNs relating to research goals and patient recruitment, and concerns regarding the patient's ability to provide informed consent. The discussion of this subtheme provides a further insight to the role that registered nurses play in clinical trials research.

The PIs in this research study described how important it was for anyone transitioning into the role of clinical trials coordination to understand the concept of research and its place in society, therefore demonstrating a commitment to clinical trials research and its underpinning philosophy. Some of the CTNs indicated that although they are aware the main objective of their position was in the recruitment and retention of patients to clinical trials, their main concern, however, is for the patient. Here the CTNs clearly demonstrate that they are being nurses, wherein they are projecting a caring attitude and a willingness to meet the patients' needs rather than the needs of the clinical trials. These actions by the CTNs may not always align with the research objectives and can therefore lead to tension between CTNs and PIs or trial sponsor.

Previous literature about CTNs has acknowledged the tension between the dual role of caregiver and researcher (Fisher 2006; Davis et al., 2002; Ecklund 1999; Di Giulio 1996; Johnson 1986). From the interview data analysed in this research study, a clearer indication emerges that the CTN fulfils several roles in clinical trials coordination and management, of which a major role in the informed consent process is apparent. Additionally, the results indicated conflicting interpretations between PIs and CTNs as to who had the ultimate responsibility for patient consent. The informed consent process also contributed to the tension between caregiving and research roles for CTNs; for example, CTNs in this study frequently expressed concerns to PIs that clinical trial protocols may not sufficiently consider patient needs. Specifically, CTNs in this study stated that they had indicated their concern

about the suitability of the clinical trial to individual patients when implementing a trial protocol and questioning whether or not the patient would benefit from participating. Some of the examples given by both CTNs and PIs in this study included consideration of the social and emotional wellbeing of patients, language barriers and physical requirements such as travel to the clinical trial site for protocol driven assessments.

Although the CTNs in this study understood the importance of enrolling and recruiting patients onto a clinical trial, they often described themselves as advocating on behalf of the patients and all of the CTNs identified patient advocacy as their primary responsibility. Previous studies have indicated that CTN commitment to patient welfare translates into an advocacy for the patient that follows on throughout the study and remains a central role for the CTN during the course of the clinical trial (Fisher 2006; David et al., 2002). Advocacy is an important concept in nursing practice and is frequently used to describe the nurse-client relationship (Gaylord and Grace 1995; Gadow 1990). For nursing, patient advocacy is not limited to the defence of patient rights, it stems from a philosophy of nursing where nursing practice is to support a patient to promote his or her own well-being, as understood by the patient (Gaylord and Grace 1995). Thus, the commitment to patient advocacy illustrates how CTNs function from a professional nursing perspective.

The views of the CTNs in this study regarding informed consent highlighted how their research roles were grounded in ethical nursing practice and knowledge. CTNs perceived informed consent as a complete process and paid particular attention to delivering information and clarifying the impact of trial participation on the patient. Consistent with the literature, CTNs saw themselves not only recruiting participants, but also providing care to those patients recruited to the trial (Mueller and Mamo, 2002) utilising the values, ethics and

beliefs consistent with *Being a Nurse*. Nursing background, professional knowledge and ethical principles therefore informed their practice as a CTN.

Previous studies have indicated that CTNs understand how their role influences the informed consent process, and particularly how the quality of their interaction with the patients affects patient recruitment, enrolment and retention in clinical trials (Fisher 2006; Wright et al., 2002). Most of the PIs agreed that having a nurse in the role of clinical trial coordinator was advantageous. The PIs expressed this aspect because they noticed that nurses functioned from within their professional nursing background which included developing and maintaining trust and rapport with patients. One PI in this study stated that nurses should be utilised if the clinical trials were of a complex nature because nurses would be able to apply their critical thinking and ethical judgement to the clinical trials research process. The CTNs in the study described the importance of maintaining rapport with the patient to ensure the continuity of their trial participation. Continued participation of patients on clinical trials to completion is crucial because this delivers important data at the end of the study necessary for testing the effectiveness of the intervention (Friedman et al, 2010)

Despite the fundamental role that CTNs play in the informed consent process, they are often left out of discussions regarding ethics in clinical trials at the protocol design stage (Fisher 2006; Wright et al., 2002; Tattersall 2002). This is unfortunate as involving CTNs from the initial stages of clinical trial protocol development also enables CTNs to contribute towards a more patient-friendly study design (Davis et al 2002; Ocker and Plawik 2000). A few studies (Loh et al., 2002; Davis et al., 2002; Tattersall 2002; Wright et al., 2002) have reported in both the medical and nursing literature on the positive influence that CTNs have in the informed consent process. These studies have suggested further investigations are needed to evaluate the full impact that CTNs have upon the informed consent process in clinical trials

research. Further research will evaluate whether nurses utilising their professional nursing background have a positive impact to the informed consent process. The next section will discuss the second subtheme found in this study; therapeutic knowledge and clinical skills.

5.1.2 Applying Therapeutic Knowledge and Clinical Skills

Registered nurses are able to make a unique contribution to the conduct of clinical trials as they are able to marry their clinical nursing knowledge and skills with research skills within the particular therapeutic discipline of clinical trials practice. CTNs provide quality of care for patients and their families by applying their knowledge of disease and symptom control and their nursing skills in clinical decision making and problem solving to the care of patients enrolled on trials. This section discusses how CTNs apply therapeutic knowledge and clinical nursing skills within their clinical trials nursing role.

CTNs in this study reported constantly assessing their patients, monitoring them and deriving clinically related data as well as research data related to the clinical trial. This exemplifies CTNs using the therapeutic knowledge and clinical skills that they bring into the clinical trials role (Nagel et al., 2010; Hill and MacArthur 2006) and how these are grounded within their professional nursing framework. The skills and characteristics related to providing nursing care identified in the nursing literature are also displayed by CTNs in their role in clinical trials. McCance (2003) summarises these skills as professional competence, interpersonal skills, personal characteristics and commitment to the job.

CTNs portray these skills and characteristics through the various aspects of their role, for example when they are performing technical aspects like venepuncture, physical assessment, educating patients, listening to them, being friendly and open and showing interest in the patient and their background (Nagel et al., 2010; Hill and MacArthur 2006; Roberts et al.,

2006; Rico-Villademoros et al., 2004; Mueller and Mamo 2002). Professional competence in nursing focuses on the skills of the nurse in relation to the physical or technical aspects of care and the ability of the nurse to prioritise their work load as perceived by the patient (McCance, 2003). Nurses stepping into a clinical trials role are often from a clinical specialist background and have extensive clinical expertise and experience, therefore bring with them a wealth of knowledge and clinical skills that they can utilise in their clinical trials nursing role (Roberts et al., 2011; Bell 2009; Hill and MacArthur 2006; Rickard et al., 2006; Rico-Villademoros 2004). The PIs in this study, as well as other studies reported in the medical literature (Wright et al., 2002; Loh et al., 2002; Eaton and Pratt 1990) state that CTNs are employed in trial coordinator positions because they demonstrate this combination of professional expertise and skill.

In demonstrating professional expertise and experience, the CTNs depict confidence in their work which patients observe, and therefore may potentially lead to enhanced clinical trials participation. McCance (2003) identified links between professional competence and the experience of the nurse as an influencing factor on the confidence engendered in the patient. Mueller and Mamo (2002) give examples of how CTNs in their study provided care by performing nursing functions such as physical assessment, education and advocacy and connecting with their patients on an emotional level. Another example that these authors describe is how CTNs use their interpersonal skills to get to know their patients to develop and implement health education strategies (Mueller and Mamo 2002).

The effective use of interpersonal skills was described by the CTNs and PIs participating in the current study as an important contributing factor to the successful conduct of clinical trials. CTNs use their interpersonal skills in the role of educator for the patient and family, and for other healthcare professionals associated with the clinical trial (Bell 2009; Ocker and

Plank 2000). Utilising their knowledge in disease and symptom management, the CTNs convey information in an environment that is supportive and safe.

The CTNs enable the process of creating a supportive and safe environment by providing patients time and assurance during the informed consent process (Poston and Buescher 2010; Fisher 2006). The CTNs have an obligation to provide safe and supportive care as it is part of their professional nursing undertaking. They are able to draw upon their nursing knowledge and skills to ensure that the patient receives the right information at the right time and in the right format. Furthermore, the CTNs take time to answer patients' queries and acknowledge that if they are unable to answer or require further clarification, they will undertake to do so. CTNs are guided by their nursing knowledge and skills when facilitating information flow to the patient. The CTNs in this study constantly referred to the importance of listening to patients, giving patients up to date information, obtaining correct information for patients and ensuring that practices were guided by international good clinical practices. They also use their interpersonal skills as they manage and coordinate clinical trials, by establishing and maintaining contact with the ethics committee, other clinical trials centres, the study sponsor, other key stakeholders and most importantly the PI. These findings are also supported by literature (Poston and Buescher 2010; Bell 2009; Yin 2008; Cantini and Ells 2007; Rickard et al., 2006; Fisher 2006; Mueller 2001).

These interpersonal skills are part of the ability of the CTN to communicate a caring attitude, and this attitude was commented on by both PIs and CTNs participating in this study. This was often articulated in terms of general attitude and manner, where the CTNs displayed attentive listening, providing information so the patient can make an informed decision, honesty, patience, responsibility, comforting, sensitivity and respect. The act of caring features quite prominently in nursing philosophy and practice and can be considered as

inherent and fundamental to nursing, as well as what differentiates nursing from other health related activities (Borbasi and Jackson, 2000).

Caring in nursing has many definitions, including that of an invisible factor which is often not recognised except when it is seen in actions and attitudes (Jackson and Borbasi, 2000). Morse and colleagues (1991p. 3) identified five main views on the nature of caring, which are, 'caring as a human trait, caring as a moral imperative or ideal, caring as an emotion or affect, caring as an interpersonal relationship and caring as a therapeutic intervention'. Nevertheless, while care in nursing is multifaceted and complex it is about commitment to the wellbeing of the whole person. Watson's theory (Watson, 2003) asserts that caring interaction is achieved by helping the patient gain a higher degree of harmony within the mind, body, and soul. This leads to a holistic perspective and allows for the provision of individualised nursing care (Jackson and Borbasi, 2000).

Thus, many of the actions of the CTNs reported in this study can be understood and interpreted as nurse caring behaviours and as part of the nursing aspect of the CTN role. Nurse caring behaviours such as availability, gentleness, understanding and friendliness are reflected in the different roles that the CTNs assume in clinical trials. For example, in gaining consent, the CTN is open and spends time listening and answering patient queries honestly, which reflect a caring behaviour.

Because patients are viewed as a whole person and their needs and concerns are addressed individually, this type of action on the part of the CTN leads to the development of a trusting relationship with the patient. In this research study, the CTNs indicated that it is of utmost importance that patients feel safe and comfortable with them, in order to develop a trusting and lasting professional relationship. Establishing relationships with patients is very much a central aspect of nursing practice as nursing practice involves managing, looking out for and

ensuring that the patient has the best possible care whilst under the nurse's responsibility, regardless of the setting (Diers, 2004). CTNs are constantly monitoring patients, gathering data that are both clinically and research relevant and assessing patients both emotionally and physically to ensure that the patient is able to cope with participation in the clinical trial. The rapport with patients resulting from these actions may have a positive impact on the retention of patients thus leading to a more successful trial outcome (Fisher 2006; Mueller and Mamo 2002).

Personal characteristics are equally important in the expression of caring (McCance 2003). A few of the PIs in this study indicated that it requires someone with empathy and integrity to coordinate clinical trials and suggested that this is engendered in the nursing profession. The CTNs in this study stated that their position in clinical trials does require someone with an understanding of the disease process and an understanding of the patients' emotional and physical needs, to make the role a successful one.

In summary, a holistic, caring approach fostered by CTNs not only results in successful management of clinical trials research but also humanises the research process for the patients. This section has highlighted how the CTNs draw upon their nursing knowledge and skills in their role in clinical trials research. The CTNs facilitate the promotion of patients' wellbeing throughout the trial, using skills which are central to nursing practice through their knowledge of disease, their knowledge of the specific population under study and which include assessment, implementation and evaluation of care.

5.2 Implications

The findings of this study suggest that nurses working in clinical trials can no longer simply be perceived as research assistants who are mainly responsible for gathering clinical trial

data. With the increase in the number and complexity of clinical trials research in Australia, the CTN role has become more specialised. CTNs now hold central positions in coordinating and managing trials, as well as responsibility for trials-related patient care. As a role in transition, clinical trials nursing is still attempting to build a clear identity and position for itself within nursing and clinical research. This study has shown that nurses working in a clinical trials research position do not always have clear links with a nursing professional or organisational structure and thus do not have the opportunity to influence policy or develop leadership skills in this field.

This study has found that there is currently a lack of career structure for CTNs. Review of current literature and interview data presented in this study confirms that the CTNs often felt ill prepared in relation to their research skills. In order to maximise capacity, nursing needs to develop models for clinical academic career pathways that define leadership roles and map training routes for novice researchers in clinical trials and other research roles. To establish a career pathway, relevant and appropriate research skills training and education has to be available and accessible to CTNs in order to support them to progress in a clinical trials research role at a nationally recognised educational institute.

Clinical trials research investigators understand and appreciate the competence that nurses bring to clinical trials coordination. CTNs enter the clinical trials role from diverse clinical nursing backgrounds, as indicated by this research study. Although not all CTNs have the clinical specialty background directly related to the clinical trial, they do have a strong clinical training background and are therefore more able to make the transition into this role. CTNs are involved in educating participants in the clinical trials process and the disease interventions being studied, therefore it would appear that to achieve better outcomes for successful trial conduct, educational preparation beforehand should be more readily available.

These findings highlight the need for a tailored CTN orientation program to prepare for this role. The program should include current relevant clinical practice, up to date processes for ethics submission, guidelines and review, and certainly continuing training modules in the disease specialty that the CTN is involved in.

A major recommendation from the McKeon Review (www.mckeonreview.org.au, February 2013) was the implementation of a long-term strategic policy framework to guide and support clinical trials' workforce in order to meet Australia's clinical research workforce needs. Key elements summarised in this review include meeting demand for research skills in Australia and identifying the issues, actions and needs associated with increasing participation in Australia's research workforce.

Greater harmonisation of the CTN position description to incorporate nursing specialist practice and research would certainly enhance the quality of the workforce entering into clinical research positions. Providing remuneration according to the level of expertise in clinical and research skill would also enable greater retention of the CTN workforce and employment on a more permanent rather than temporary contractual basis. This would enable a research facility to grow with staff that is dedicated and well trained thus achieving excellence in clinical trial coordination. Also greater involvement of nurses in protocol development and the publication and dissemination of results would contribute significantly to career enhancement as CTNs would be acknowledged for their participation as researchers and be recognised for their collegial and professional practice.

5.3 Conclusion

With the increasing numbers of clinical trials and greater complexity around their design and management, nurses are being challenged to perform a more diverse role in clinical trials

research. This study has highlighted the diverse role that CTNs play in the course of clinical trials research conduct and management. During the course of conducting and managing clinical trials, CTNs draw upon their core nursing attributes, knowledge and skills as defined and described in this chapter.

The subthemes found through the interview analysis: Functioning from a Professional and Ethical Nursing Perspective and Applying Therapeutic Knowledge and Clinical Skills individually but collectively explain how CTNs essentially practice as registered nurses. The CTNs and PIs interviewed for this study describe characteristics of the CTN that reflect practices based on a professional nursing framework such as caring, autonomy, moral competency, problem solving skills and decision making skills. The CTNs transfer their nursing skills seamlessly into the clinical trial research role which enables them to practice within a nursing domain thus '*Being a Nurse*'.

However, in practising within a professional nursing framework, the challenge of marrying both a researcher and a caregiver role has arisen. In order to progress, nurses working in clinical trials roles should work to define and describe their roles and make clear distinctions between themselves and other professional groups who function in clinical trial coordination and management roles. CTNs need to network with other CTNs, form professional groups and conduct further research into their role, as well as publish frameworks or specialist competencies for their roles in order to assist others in describing, recognising and understanding the role for themselves.

Articulating the role of a CTN and recognising the dual roles and perspectives of being a nurse and a researcher are important and the first of many steps to come. This study is the first study to explore and acknowledge the dual role of CTNs (that is, nurse and clinical trials researcher) held by RNs in various clinical trial specialities. Recognising that the CTN role

requires further study enables leaders in nursing to focus and develop this unique role thus ensuring nurses can embrace clinical trial coordination roles with greater confidence and leadership.

The next chapter will summarise the major findings and implications of this study and present limitations of the research. Limitations and recommendations of this research project are discussed in the wider context before concluding.

Chapter 6: Conclusion

6.0 Introduction

In this concluding chapter the major findings are summarised. Limitations and recommendations of this research project in its wider context are also discussed. The primary aim of this study is to contribute to the understanding of the role of registered nurses working in clinical trials research who for this study have been labelled as clinical trials nurses (CTN). This is a qualitative, interpretive research study conducted to gain a deeper perception of what it is to be a CTN in the Australian context. Little is known of the role of CTNs and their relative contribution to clinical trials research in Australia. This research study is the first investigation of its kind to better understand the contributions made and challenges faced by CTNs in Australia.

6.1 Summary of Findings

This research study has examined the role of CTNs in conducting and managing clinical trials in two large metropolitan public hospitals in New South Wales, Australia. Semi structured interviews were conducted to gain CTNs' and PIs' perspective of the CTNs role. Data analysis was conducted according to principles of Gadamerian hermeneutics, and revealed two subthemes *Functioning within a Professional and Ethical Nursing Framework* and *Applying Therapeutic Knowledge and Clinical Skills*, contributing to an overall theme *Being a Nurse*. The themes provide illuminating insights into the experiences of nurses working in a different and challenging nursing role, from the perspective of both CTNs and PIs. Each of the themes that emerged from the data analysed in this study, provide a lens into the world of CTNs working in clinical trials research. The two subthemes provide a detailed understanding of the role of CTNs bring together, under the overarching theme *Being a Nurse*.

The analysis of the data revealed that the CTNs in this study essentially displayed distinct attributes of nursing in their role. This main finding is not unsurprising to comprehend because they are indeed nurses by profession, with a considerable background in general nursing and specialty clinical nursing, prior to embarking on a career in clinical trials research. The CTNs conveyed their nursing traditions, philosophy, knowledge and expertise as well as their personal traditions and attributes to the clinical trials nursing role. Therefore, CTNs as nurses are shaped by their prior experiences, to care for and manage patients using nursing framework, codes and practices.

It was clear from the data that CTNs utilised their nursing skills and expertise to contribute to patient care and clinical research simultaneously. CTNs are responsible for fulfilling the requirements of the clinical trial protocol, clinical research standards and guidelines and to promote a research environment within a healthcare setting, as well as practice within a nursing framework. In essence, the CTNs in this study indicated that they adopted codes and standards of practice to the environment that they worked in, be it a clinical or clinical research setting. These research findings suggest that CTNs continue to utilise their nursing skills and expertise in their role, contributing to the care of trial participants in a variety of ways. Through playing a dual role of both caregiver and researcher, the analysis revealed that tensions arise between the enactment of these two roles, where CTNs in essence combine both a role in research alongside professional nursing roles and responsibilities. CTNs are negotiating a range of competing loyalties, due to the interplay between their professional nursing role and their role in clinical research.

The analysis of the data indicates that the CTNs bring a variety of practical, organisational and interpersonal skills to their role in clinical trials research. However, the data also suggest that the CTNs' main point of difference lies in their ethical approach to patient care and their

ability to incorporate nursing care into their clinical research role; how these factors contribute to the outcomes of clinical trials research and to the patients' experience as participants in clinical trials research is not fully known which requires further research.

The research study has identified that CTNs bring an in depth knowledge base, critical thinking, decision making skills and clinical practice that is underpinned by an ethical and professional nursing framework. Previous studies conducted in an Australian context (Roberts et al., 2011; Rickard et al., 2006) have only investigated a particular clinical specialty and not all participants were nurses. This study, however, has contributed to growing evidence concerning an approach to professional practice of CTNs in Australia by studying the perspectives of a diverse group of CTNs of different clinical specialties, obtaining the viewpoint of PIs who work with CTNs closely and using hermeneutics to gain a deep understanding of the CTN role.

6.2 Strength and Limitations of this Study

The main strengths of this study stem from the methodology used: qualitative research to investigate the role of registered nurses in clinical trial research. The investigative methods utilised in this research study are particularly suited to aims that require in depth exploration of human experiences and meanings.

Semi structured interviews were used to gain an in depth insight into their role as clinical trials nurse. The use of semi structured interviews provided the researcher with data that was reliable and comparable. A major strength of this method of interviewing was that it allowed for a two way communication, therefore enabling a process of giving and receiving information. Furthermore, this method of interviewing provided the researcher flexibility to probe for details and discuss issues as they arose. Direct interactions with the study

participants developed and facilitated good relationship with them enabling rich data to be generated. Hermeneutic strategies allowed the researcher to draw upon her own professional insight, reflecting iteratively on the language of the participants and the theoretical underpinnings of the research. As previously stated in Chapter one, the researcher is a clinical trials nurse herself, therefore able to draw upon her own experiences when listening and reading interview transcripts.

An additional strength of the study is that participants were drawn from two different professional groups that work in clinical trials research environment. One was the CTNs themselves and second medical practitioners who work closely with CTNs identified as PIs. No other research studies in Australia at present have included medical practitioners in their research study. The advantage of including PIs in the research study provided a broader and deeper understanding of the role that RN play in clinical trials research, mainly because CTN positions are currently reporting directly or indirectly to PIs as literature review and the findings of this research have established.

Further strength of this research study is that the pool of participants was drawn from a variety of clinical specialties which intensifies the exploration of the role of CTNs. Most of the studies conducted in Australia and internationally as reflected in Table 2.4 (Appendix E) explored one group of clinical speciality such as Oncology rather than an array of clinical specialities. In exploring various clinical specialities that the CTNs work in, the present study offers an in depth understanding of the role that RNs play in clinical trial research. Consequently, the present study findings are transferable to outside this study setting.

A limitation of the study is that two of the participants were known to the researcher as they had worked together previously in similar roles. However, the insights provided by the

researcher gained directly from her knowledge of what some of the participants had undertaken in their clinical trials role, may alternatively be seen as a way of enhancing and enriching the quality of the data. As a CTN herself, the interpretation of the data is framed from her own professional background and hence what is viewed of the data will be different to that of a non-CTN or someone who has no experience in this context.

The researcher acknowledges and recognises that her own experiences are considered an asset to the type of methodology used in this research study, as her experiences provide an important contribution that assists with the interpretation of the data. In addition, the use of direct quotes taken from the transcripts to support the interpretation helps to assure the rigour of the findings and assist the reader to connect the voice of the participants with the researcher's interpretation.

One other limitation was what one can achieve in the given time frame. In this study, challenges related that of a protracted ethics submission and approval processes were encountered. The ethics submission for this research study took longer than anticipated due to the length of time and number of ethics applications that had to be processed and submitted. The study was conducted in hospitals belonging to one area health which is Sydney and South West Area Health Service. The study had to first gain approval through the University of Sydney Ethics Committee before even applying to the appropriate Area Health Service ethics committees. Once University of Sydney HREC approved the study, application was made to the Area Health Service HREC. However, the researcher was then informed that simultaneous applications to the hospitals within the same Area Health Service were not permitted. This process took six to eight months to complete which impacted upon the timeframe for the conduct of the research study and specifically data collection. The ethics

process has since changed in New South Wales to allow for single submissions to multi-centre sites.

Whilst the findings of the research are immediately applicable in the world of CTNs in Australia, it must be acknowledged that this relates to specific research settings. It is not clear if the findings can be generalised to other research settings and countries where work environments are different. Nevertheless the study raises questions and points to a need for further research in broader settings.

6.3 Further Research Recommendations

Further research is required in order to deepen the understanding of the evolving role of CTNs. The study has identified several major challenges in current CTN practice and clearly further research is required in this evolving role of CTNs. Such research could prove to be useful to nurse educators and leaders interested in the advancement of nursing's professional status in the division of health care labour as well as those nurse educators and leaders interested in advancing the role and practice domain of nursing in clinical trials research. Two lines of research should be conducted. First, comparative studies of the roles and work related tasks and skills of nurses and non-nurse trial coordinators should be undertaken. Such studies would be useful in delineating the role of CTNs in clinical trials research and in developing educational programs for both nurses and non-nurse careers in the domain of clinical research. Second, explorations of ethical conflicts and resolutions should be undertaken specific to the role that CTNs play in clinical trials research as it would make important contributions to policy development of ethics and practice of human centred biomedical research.

Another area of future research is the assessment of CTNs' influence over the recruitment of patients into clinical trials research. Participants in this study and anecdotal literature have

alluded that CTNs (Scott et al 2011, Bell 2009, Yin 2008, Stephens Lloyds 2004, Waller 2003, Davis et al 2002) have a unique role in the process of recruiting patients to active clinical trials. Further research to validate this impression is required, because, ultimately, a greater understanding of the relative role of CTN factors will be important in the development of ethical and supportive strategies to optimise the recruitment of patient into clinical trials research.

6.4 Recommendations for Practice

The findings of this research study emphasises the need to establish a clear definition and description of the CTN role as an essential starting point for developing the role further. Without greater clarity, it is difficult to develop appropriate career pathways, improve opportunities for relevant educational and professional development and greater recognition for the role. Absence of career structure is identified as a major professional issue by the CTNs in this research study.

Recommendation 1

The increasing national investment in research, strategic emphasis on research governance and requirement to demonstrate quality patient care means it has never been more important that nurses with research expertise inform organisational and local research policy. The study has shown that CTNs do not always have clear links with nursing structures and thus do not have the opportunity to influence policy or develop leadership skills.

Multi agencies including policy makers, clinical research industry and ANMC should facilitate CTNs to develop a leadership role and encourage input at a strategic and operational level.

Recommendation 2

Within the CTN cohort there is a variety of job titles, grades and levels of responsibility. This situation creates uncertainty around accountability and responsibility both for staff to assume, for the organisation to expect and for the organisation to adopt for this nursing cohort. For professional indemnity it is important that clear lines of responsibility are outlined.

There should be a single approach to recruitment of CTNs including harmonisation of job titles, job descriptions to clarify roles and responsibilities and remuneration standardisation across Australia.

Recommendation 3

Research governance requires all members of the research team be qualified by education, training and experience to perform their tasks. This study has shown wide variation in job descriptions, assumed levels of responsibility and preparation for the role in terms of education and training.

There should be consensus around a set competency standards for all CTNs.

Recommendation 4

Relevant and appropriate research skills training and education has to be available and accessible to CTNs in order to support the achievement of competent research activity and high quality clinical practice.

There needs to be provision of training and education for research skills to enable the achievement of competency in conducting, designing and leading research.

Recommendation 5

The majority of CTNs are involved in the central elements of the research process: participant identification, recruitment, delivery of interventions, assessments and procedures and data collection. To a lesser extent they are also involved in the polar ends of the clinical research

process including, protocol development, trial reporting and dissemination. Few CTNs are involved in the publication of the research they are involved in.

CTNs should be encouraged and supported by the organisations that they work in to be active proponents in all stages of the research process, from protocol development to publication and dissemination of results.

6.5 Conclusion

The role of the CTN is diverse, dynamic and integral to the clinical trials process. It is still a role in transition; therefore no agreed definitions exist to the job title or description. This research study has identified that CTNs distinctly convey nursing traditions and philosophy in their role in clinical trials research. The CTNs in this study described and discussed their professional nursing role which included consent process as underpinned by ethical and professional nursing. The research study also revealed that CTNs use nurse orientated input into clinical trials research such as in depth knowledge base, critical thinking, clinical skills and decision and problem solving skills. The research study revealed that CTNs appear to hold a dual role as both researcher and caregiver.

CTNs practising in the clinical trials research need to define and clarify their role. The development of a career structure is hindered by the proliferation of titles currently used by CTNs. There needs to be a clear career structure and pathway which would allow CTNs to develop their practise and make clear distinctions between them and other professional groups who function as coordinators, but not as nurses. It is imperative that the nursing profession determines the appropriate career pathway for nurses pursuing a career in clinical trials research; otherwise they may find others doing it for them.

Reference

- Abulad, R.E. (2007) *What is Hermeneutics?* *Kritike* 1(2) 11-23, Retrieved from www.kritike.org
- Access Economics (2008) *Exceptional Returns: The Value of Investing in Health R&D in Australia. Report for the Australian Society for Medical Research*, Canberra
Retrieved from www.accesseconomics.com.au/publicationsreports/showreport
- Australian Institute of Health and Welfare (2010). *Health Expenditure Australia 2008-09*. Cat. no. HWE 51. Canberra: AIHW.
- Australian Institute of Health and Welfare (2009). *Health Expenditure Australia 2007-08*. Cat. no. HWE 46. Canberra: AIHW.
- Beller, E., Gebiski, V., & Keech A.C. (2002). Randomisation in clinical trials. *Medical Journal of Australia* 177 (10), 565-567.
Retrieved from <http://www.mja.com.au>
- Binding, L.L., & Tapp, D.M. (2008). Human understanding in dialogue: Gadamer's recovery of the genuine. *Nursing Philosophy*, 9 (2), 121-130.
- Bird, J., & Kirshbaum, M. (2005). Towards a framework for advanced practice for the clinical research nurse in cancer care. *Clinical Effectiveness in Nursing*, 9, 161-171.
- Bloom, G.,S. & Frew, D. (2009). Regulation of research through research governance: within and beyond NSW Health. *N S W Public Health Bull*, 19(11-12),199-202.
- Brody, H., & Miller, F. G. (2003). The clinician-investigator: Unavoidable but manageable tension. *Kennedy Institute of Ethics Journal*, 13(4), 329-346
- Burns, N., & Grove, S.K. (2003) *Understanding Nursing Research 3rd edition*. United States of America:W.B Saunders.
- Chadderton H (1997) Hermeneutics: Present, past and future. *Nursing Times* 2(6) 402-404.
- Crotty, M. (1998). *The foundations of social science research*. St. Leonards, New South Wales: Allen & Unwin.
- Davis, A., Hull, S., Grady, C., Wilfond, B., & Henderson, G. (2002). The invisible hand in Clinical Research: The study co-ordinator's critical role in human subject protection. *Journal of Law, Medicine, & Ethics*, 30, 411-419.
- Department of Health and Ageing Budget Statement 1999-2000*, Canberra
Retrieved from <http://www.health.gov.au>
- Deave, T. (2005). Research nurse or nurse researcher: How much value is placed on research undertaken by nurses? *Journal of Research in Nursing*, 10(6), 649-657.

- Debesay J., Naden, D. & Slettabo, A. (2008). How do we close the hermeneutic circle? A Gadamerian approach to justification in interpretation in qualitative studies. *Nursing Inquiries* 15(1), 57-66
- Downs, M., Tucker, K., Chris-Schmidt,H., & Wittes, J. (2010) Some practical problems in implementing randomisation. *Clinical Trials*, 7(3), 235-245.
- Duane, C., Granda, S., Munz, D., & Cannon, J. (2007). Study co-ordinators' perceptions of their work experiences. *The Monitor*, 21(5), 39-42.
- Eaton, L. (2006). Norwegian researcher admits that his data were faked. *British Medical Journal*, 332: 193
- Eckland, D. (1999). Establishing a research co-ordinator network: The birth of an idea. *Journal of Nursing Administration*, 29(1), 20-25.
- Ehrenberger, H., & Lillington, L. (2004). Development of a measure to delineate the clinical trials research nursing role. *Oncology Nursing Forum*, 31(3), E64-E68.
- Engelking, C (1991). Facilitating Clinical trials research: The Expanding Role of the Nurse. *Cancer* (67) March 15: 1793-1797
- Fagermoen, M.S. (1997). Professional identity : values embedded in meaningful nursing practice. *Journal of Advanced Nursing*, 25(3), 434-441.
- Federal Drug Authority. (2009) *Vioxx and Drug Safety*. Retrieved from <http://www.fda.gov/newsevents/testimony/ucm113235.htm>
- Fisher, J. (2006). Coordinating 'ethical' clinical trials research: The role of research coordinators in the contract research industry. *Sociology of Health & Illness*, 28(6), 678-694.
- Friedman, L.M., Furberg, C.D., & Demets, D.L. (2010). *Fundamentals of Clinical trials research 4th Edition*. New York: Springer,
- Forder, P.M., Gebski, V.J., & Keech, A.C. (2005). Allocation concealment and blinding: when ignorance is bliss. *Medical Journal Australia*, 182 (2), 87-89. Retrieved from <http://www.mja.com.au>
- Gadamer,H.G. (1989) *Truth and Method*. Crossroad Publication
- Gallin, J.I., & Ognibene, F.P. (2012). *Principles and Practices of Clinical Research*. United States of America: Academic Press
- Geanellos, R. (1998). Hermeneutic philosophy. Part I: implications of its use as methodology in interpretive nursing research. *Nursing Inquiry*, 5(3), 154-163.

- Geanellos, R. (1998). Hermeneutic philosophy. Part II: a nursing research example of the hermeneutic imperative to address forestructures/pre-understandings. *Nursing Inquiry* 5(4), 238-247.
- Gerber, P. (2006). What can we learn from the Hwang and Sudbo affairs? *Medical Journal Australia*, 184 (12), 632-635. Retrieved from <http://www.mja.com.au>
- Girard, F., Linton, N., & Besner, J. (2005) Professional Practice in Nursing: *Nursing Leadership* 18(2), 2005
- Gubrium, J.F., & Holstein, J.A. (2001) *Handbook of Interview Research Context and Method*. United States of America: Sage Publications
- Haigh, C., Neild, A., & Duncan, F. (2005). Balance of power--do patients use researchers to survive hospital? *Nurse Researcher*, 12(4), 71-81.
- Harlan, W.R (2008). *Clinical trials research: International Encyclopedia of Public Health: 744-754*, United States of America :Elsevier Science & Technology
- Hart P (1999). A change in scientific approach: from alternation to randomised allocation in clinical trials in the 1940s. *British Medical Journal*, August 28; 319(7209): 572–573.
- Haynes, M., & Dada, J. (2002). Nurses in research: the treatment of acne. *Nursing Standard* 16(31): 33-36.
- Hill, G., & MacArthur, J. (2006). Professional issues associated with the role of the research nurse. *Nursing Standard*, 20(39), 41-47.
- Hodges, L.C., Patterson, R., & Rapp, C.G. (1990). Clinical trials research: The role of the Neuroscience Nurse." *Journal of Neuroscience Nursing* 22(3): 195-198.
- Huntington, I., & Robinson, W. (2007). The many ways of saying yes and no: Reflections on the research co-ordinator's role in recruiting research participants and obtaining informed consent. *IRB: Ethics & Human Research*, 29(3), 6-10.
- Jeong, Ihnsook; Kang, Hyun-Sook; Kim, Won-Ock (2007) Clinical Research Nurses: *Roles and Qualifications in South Korea Drug Information Journal* 41 (2), 251-256
- Johnson, J.M. (1986). Clinical trials research: New responsibilities and roles for nurses. *Nursing Outlook* 34(3): 149-153
- Kerr, D. J., Knox, K., & Robertson, D. (2008) *Clinical trials research Explained: A Guide to Clinical trials research in the NHS for Healthcare Professionals*. Great Britain: Wiley.
- Kenkre, J., & Foxcroft, D. (2001). Career pathways in research: Clinical research. *Nursing Standard*, 16(5), 41-44.
- Koch, T. (1996). Implementation of a hermeneutic inquiry in nursing: Philosophy, rigor, and representation. *Journal of Advanced Nursing*, 24, 174-184.

- Koch, T. (1999). An interpretive research process: Revisiting phenomenological and hermeneutical approaches. *Nurse Researcher*, 6(3), 20-34.
- Legge, S. (2004). The research nurse in orthopaedics. *Journal of Orthopaedic Nursing*(8):20-24.
- Loh, W., Butow, P.N., Brown, R.F., & Boyle, F. (2002). Ethical communication in clinical trials research: Issues faced by Data managers in obtaining informed consent. *Cancer* 95(11): 2414-2421.
- McCance, V., (2003). Caring in nursing practice: The development of a conceptual framework. *Research and Theory for Nursing Practice*, 17(2), 101-116
- McDonald, E., Clarke, F., Dale, C., Davidson, C., Farrell, R., Hands, L., et al. (2005). ICU research co-ordinator activities: A time-in-motion multicenter study. *Critical Care*, 9(Suppl 1), 267.
- Minichiello, V. (1995). *In-Depth Interviewing: Principles, Techniques, Analysis*, Longman Publishing Group.
- Mori, C., Mullen, N., & Hill, E. (2007). Describing the role of the clinical research nurse. *Research Practitioner*, 8(6), 220-228.
- Mueller, M. (2001). From delegation to specialization: Nurses and clinical trial co-ordination. *Nursing Inquiry*, 8(3), 182-190.
- Mueller, M., & Mamo, L. (2000). Changes in medicine, changes in nursing: Career contingencies and nurses in clinical trials research co-ordination. *Sociological Perspectives*, 43(4), S43-S57.
- Mueller M., & Mamo, L. (2002). The nurse clinical trial co-ordinator: Benefits and drawbacks of the role. *Research and Theory for Nursing Practice: An International Journal*, 16(1), 33-42.
- National Health and Hospitals Reform Commission Report (2009). *A Healthier Future for All Australians*, Commonwealth of Australia
- NHMRC levels of evidence and grades for recommendations for developers of guidelines* (2009). Retrieved from <http://www.nhmrc.gov.au>
- NHMRC Research Funding 2003-2012 (2013)*. Retrieved from http://www.nhmrc.gov.au/grants/datasets/_files/clinical.xls
- National Statement on Ethical Conduct in Human Research (2007)* Retrieved from <http://www.nhmrc.gov.au>
- Nesbitt, L.A. (2004). *Clinical Research: What it is and how it works*. Canada: Jones and Bartlett Publishers

- Namei, S., King, M., Bryne M., & Proffitt, C. (1993). The Ethics of Role Conflict in Research. *Journal of Neuroscience Nursing* 25(5): 326-330.
- Ocker, B., & Pawlik Plank, D. (2000). The research nurse role in a clinic-based oncology research setting. *Cancer Nursing*, 23(4), 286-292.
- Packer, M. (1985). Hermeneutic inquiry in the study of human conduct. *American Psychologist*, 40(10), 1081-1093.
- Paterson, M., & Higgs, J. (2005). Using hermeneutics as a qualitative research approach in professional practice. *The Qualitative Report*, 10(2), 339-357.
- Phillips, B. (2007). Nursing care and understanding the experiences of others: A Gadamerian perspective. *Nursing Inquiry* 14(1), 89-94
- Piantadosi, S. (2005). *Clinical trials research: a methodological perspective*. USA: John Wiley and Sons Publishers.
- Polit, D.F., & Beck, C.T. (2006). *Essentials of Nursing Research: Methods, Appraisal and Utilization 6th Edition*, Philadelphia USA: Lippincott Williams and Wilkins
- Pocock, S.J (1983). *Clinical trials research: A Practical Approach*. USA: Wiley Publishing
- Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100).*
- Raja-Jones, H. (2002). Role boundaries--research nurse or clinical nurse specialist? A literature review. *Journal of Clinical Nursing*, 11, 415-420.
- Rath, L., Hitchcock, A., Oakley, M., & Graham J (2003). Clinical drug trials and the role of the nurse. *Australian Nursing Journal (Update)*. May 2003: CU1
- Raybuck, J. A. (1997). The Clinical Nurse Specialist as a Research Coordinator in clinical drug trials. *Clinical Nurse Specialist* 11(1): 15-18.
- Rice, P. L., P. Liamputtong, et al., (1999). *Qualitative research methods: a health focus*, Oxford University Press.
- Rico-Villademoros, F., Hernando, T., Sanz, J., Lopez-Alonso, A., Salamanca, O., Camps, C., et al. (2004). The role of the clinical nurse research co-ordinator--data manager--in oncology clinical trials research. *BMC Medical Research Methodolgy*, 4(6).
- Rickard, C., Roberts, B., Foote, J., & McGrail, M. (2006). Intensive care research co-ordinators: Who are they and what do they do? Results of a binational survey. *Dimensions of Critical Care Nursing*, 25(5), 234-242.

- Rickard, C., Roberts, B., Foote, J., & McGrail, M. (2007). Job satisfaction and importance for intensive care unit research co-ordinators: Results from binational survey. *Journal of Clinical Nursing*, 16, 1640-1650.
- Roberts, B., Rickard, C., Foote, J., & McGrail, M. (2006). The best and worst aspects of the ICU research co-ordinator role. *Nursing in Critical Care*, 11(3), 128-135.
- Sackett, D. (2000). *Evidence-based Medicine: How to practice and teach EBM*. Edinburgh
- Saks, M., & Allsop, J. (2007). *Researching Health: Qualitative and mixed Methods*. London: Sage Publisher
- Sadler, G., Lantz, J., Fullerton, J. & Dault, Y. (1999). Nurses' unique roles in randomized clinical trials research. *Journal of Professional Nursing*, 15(2), 106-115.
- Sandelowski, M. (1986). The problem of rigour in qualitative research. *Advances in Nursing Science*, 8(3), 27-37.
- Sastry, S., Daly, K., Chengodu, T. & McCollum, C. (2007) Is Transcranial Doppler for the Detection of Venous-to-Arterial Circulation Shunts Reproducible? *Cerebrovascular Diseases*: 3(5-6): 424-9. Epub 2007 Apr 2.
- Schneider, Z., & Whitehead, D. (2007) *Nursing and Midwifery Research : Methods and appraisals for evidence based practice, 4th edition*. Elsevier Australia
- Scott K, White K, Johnson C, & Roydhouse J. (2011) Knowledge and Skills of Cancer Clinical Trials Nurses in Australia. *Journal of Advanced Nursing*, 68(5), 1111-1121.
- Spilsbury, K., Petherick, E., Cullum, N., Nelson, A., Nixon, J., & Mason, S. (2008). The role and potential contribution of clinical research nurses to clinical trials research. *Journal of Clinical Nursing*, 17(4), 549-557.
- Stephens-Lloyd, A. (2004). The extended role of the clinical research nurse: Building an evidence base for practice. *NT Research*, 9(1), 18-27.
- Strauss, S.E (2005). *Evidence-based medicine: how to practice and teach EBM*. Elsevier/Churchill Livingstone.
- Sung, N.S., Crowley, W.F., Genel, M., Salter, P., Sandy, L., Sherwood, L.M., ...Rimoin, D. (2003). Central Challenges Facing the National Clinical Research Enterprise. *Journal of the American Medical Association*, 289(10):1278-1287
- Tattersall, M. (2002), Cancer clinical trial recruitment: the emerging role and perspectives of clinical research associates and data managers. *Cancer*. 95, 1397-1400.
- Thompson, A., Pickler, R., & Reyna, B. (2005). Clinical co-ordination of research. *Applied Nursing Research*, 18, 102-105.
- Thompson, J. L. (1990). Hermeneutic Inquiry. In L. E. Moody (Ed.). *Advancing nursing science through research* (vol. 2) (pp. 223-280). Newbury Park: Sage Publications.

- Waller, J. (2002). An insight into the role of the clinical trials research co-ordinator. *Australian Nursing Journal*, 10(6), 17-18.
- Walsh, K. (1996). Philosophical hermeneutics and the project of Hans Georg Gadamer: implications for nursing research. *Nursing Inquiry*, 3(4), 231-237.
- White-Hershey D and Nevidjon B (1990). Fundamentals for Oncology Nurse/Data Managers - Preparing for a new role. *Oncology Nursing Forum* 17(3): 371-377.
- Wright J.R., Crooks D., Ellis P.M., Mings D. & Whelan T.J. (2002) Factors that influence the recruitment of patients to Phase 111. *Studies in Oncology*. 95(7) 1584-1591.
- World Health Organisation International Clinical Trials Research Registry Platform*
Retrieved from <http://www.who.int>
- World Health Organisation (1986) Ottawa Charter for Health Promotion*
Retrieved from <http://www.who.int>
- Wilkes, L., Jackson, D., Miranda, C. & Watson, R. (2012) The role of clinical trial nurses: An Australian perspective. *Collegian*. 19(4), 239-246.
- Willems Y. (1990). Cancer Care and the research nurse. *Nursing Standard* 5(6): 30-32.
- Woodin, K.E., (2004). *The CRC's guide to coordinating clinical research*, Thomson CenterWatch .
- Yin, C. (2008). Improving the quality of clinical research: Recognizing issues in Training. *Research Practitioner*, 9(1), 20-23.

Appendices

Appendix A: Interview questions for Clinical Trials Nurses:

GUIDELINE ONLY

1. How did you become a clinical trial nurse?
-Describe experience in clinical nurse
-Why this role?
2. Tell me about your role and responsibilities as a clinical trials nurse.
3. Do you play any part in the process of gaining informed consent for clinical trials?
4. Please describe how this role differs from that of the medical practitioner obtaining informed consent?
5. Tell me about the information that you routinely give to patients about clinical trials and the issues that you may or may not discuss with patients.
6. Do you find that patients ask you questions that you feel are better addressed by their physicians during the consent process?
7. In your professional opinion, who should questions about clinical trials be directed to?
8. Could you describe any concerns you might have about the way in which informed consent is obtained by medical practitioners?
9. Would you be confident in gaining informed consent yourself if permitted?
10. Do you see yourself as a patient advocate?
11. If you were offered training in this area, what aspects would you like covered?
12. Who do you think is the best person to fulfill your current role?
13. Do you see the role of clinical trials nurse changing in the future?

Interview questions for Medical Practitioners involved in Clinical Trials:

1. How do you perceive the role of clinical trials nurses?
2. Please describe what is your role in the process of gaining informed consent to clinical trials?
3. Would you feel confident and comfortable with clinical trial nurses gaining consent to clinical trials? Please elaborate.
4. Please describe your working relationship with clinical trials nurses.
5. What qualifications do you see clinical trials nurses equipped with?
6. Do you see clinical trials nurses as patient advocates?
7. Do you think that clinical trials nurses are an important asset to the success of clinical trials?
8. In your professional opinion, do you see clinical trial nurses as an important asset to the success of a clinical trial?

Appendix B1: Participant Informed Consent for Clinical Trials Nurses

CLINICAL TRIALS NURSES AND THE INFORMED CONSENT PROCESS PARTICIPANT INFORMATION STATEMENT FOR CLINICAL TRIALS NURSES

You are invited to take part in a research study *Clinical trials nurses and the informed consent process: exploration of the role*. The object of this study is to define the role of clinical trials nurses and to explore their part in gaining consent in clinical trials. The study is being conducted by Thili Chengodu and will form the basis for the degree of MPH at the Faculty of Nursing and Midwifery, University of Sydney under the supervision of Professor Kate White, Dr Susan Jones and Professor John Thompson

If you agree to participate in this study, you will be asked to participate in an interview with the researcher. This interview will explore your experiences as a clinical trials nurse, your working relationship with other health professionals within your team and the process of gaining consent for trial participation from eligible patients. The interview will take 30 to 45 minutes and, with your permission, the interview will be recorded on tape and will be transcribed and analysed soon after completion of the interview. You will be given a pseudonym to protect your identity and only the researchers will have access to the tapes which will be stored in a locked facility in the Faculty of Nursing and Midwifery, University of Sydney. You will be invited to attend the Faculty of Nursing and Midwifery for the interview or may choose somewhere more convenient to you, at a time suitable for you.

All aspects of the study, including the findings, will be strictly confidential and only the investigators named above will have access to information on participants. Papers from the study will be submitted for publication but individual participants will not be identifiable. Participation in this study will not bring direct benefit to you. However, by assisting in the research study, you will be part of the wider nursing community that constantly endeavours to define its role and responsibilities in terms of nursing practice. You are welcome to discuss this research study with anyone you choose. It will not affect the outcome of the study.

Participation in this study is entirely voluntary. You are not obliged to participate and, if you do participate, you can withdraw at any time. Whatever your decision, it will not affect your relationship with the researchers or the University of Sydney.

When you have read this information, Thili Chengodu will be pleased to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Professor Kate White on 9351 0778 or Thili Chengodu on 0415 536 003 or 9351 0581. This information sheet is for you to keep and thank you for your time in reading it. We hope that you will be interested in participating in this study.

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.

Appendix B2: Participant Informed consent for Medical Practitioners

CLINICAL TRIALS NURSES AND THE INFORMED CONSENT PROCESS PARTICIPANT INFORMATION STATEMENT FOR MEDICAL PRACTITIONERS INVOLVED IN CLINICAL TRIALS

You are invited to take part in a research study *Clinical trials nurses and the informed consent process: exploration of the role*. The object of this study is to define the role of clinical trials nurses and to explore their part in gaining consent in clinical trials. The study is being conducted by Thili Chengodu and will form the basis for the degree of MPH in the Faculty of Nursing and Midwifery, University of Sydney under the supervision of Professor Kate White, Dr Susan Jones and Professor John Thompson

If you agree to participate in this study, you will be asked to participate in an interview with the researcher. You will be asked about your views on the role of clinical trials nurses, your working relationship with them and the process of gaining consent for trial participation from eligible patients. The interview will take 20 to 30 minutes and, with your permission, the interview will be recorded on tape and will be transcribed and analysed soon after completion of the interview. You will be given a pseudonym to protect your identity and only the researchers will have access to the tapes which will be stored in a locked facility in the Faculty of Nursing and Midwifery, University of Sydney. You will be invited to attend the Faculty of Nursing and Midwifery for the interview or may choose somewhere more convenient to you, at a time suitable for you.

All aspects of the study, including the findings, will be strictly confidential and only the investigators named above will have access to information on participants. Papers from the study will be submitted for publication but individual participants will not be identifiable. Participation in this study will not bring direct benefit to you. However, it will assist the researchers to better understand the role of clinical trials nurses and the working relationship that principal investigators have with clinical trials nurses. This information may, in future, be of assistance to both nurses and principal investigators in their various roles within the clinical trials team. You are welcome to discuss this study with anyone you choose. It will not affect the outcome of the study.

Participation in this study is entirely voluntary. You are not obliged to participate, and if you do participate, you can withdraw at any time. Whatever your decision, it will not affect your relationship with the researchers or the University of Sydney. When you have read this information, Thili Chengodu will be pleased to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Professor Kate White on 9351 0575 or Thili Chengodu on 0415 536 003 or 9351 0581. This information sheet is for you to keep and thank you for your time in reading it. We hope that you will be interested in participating in this study.

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney South West Area Health Service. Any person with concerns or complaints about the conduct of this study should contact the Secretary on (02) 9515 6766 and quote protocol number X05-0087

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.

Appendix C: Consent Form

CONSENT FORM

I, , give consent to my participation in the research project:

Name (please print)

Clinical trials nurses and the informed consent process

In giving my consent I acknowledge that:

1. The interview required for the project have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.
3. I understand that I can withdraw from the study at any time, without affecting my relationships with the researcher(s) and the University of Sydney now or in the future.
4. I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.

Signed: **Date:**

Name:

CALLING ALL RESEARCH NURSES

**ARE YOU CURRENTLY WORKING IN
TRIALS?**

**HAVE YOU WORKED IN TRIALS
BEFORE?**

**WOULD YOU LIKE TO SHARE YOUR
EXPERIENCES WORKING IN A TRIAL?**

**If you are, we would like to invite you to join a study investigating
the role of clinical trials nurse.**

**CALL THILI CHENGODU ON
93510562 or 0415 536 006**

**This study has been approved by the University of Sydney
Human Research Ethics Committee**

Appendix E: Table 2.4: Summary of Empirical Studies on Role of Registered Nurses Working in Clinical Trial Coordination Roles

Author	Year	Country	Method	Description	Sample	Conclusion
Wilkes et al	2012	Australia	Quantitative-questionnaire	To determine the scope and contribution of the role that clinical trial nurses play in clinical trials in Australia and also to explore professional issues	N=67	The results of the survey highlights the complexities of the professional role of the CTNs.
Scott et al	2011	Australia	Questionnaire and Focus Group	To evaluate the knowledge and skills of cancer clinical trials nurses in Australia and to gain a better understanding of their educational and training needs.	N=61	A national survey data is reported to be reliable and valid. The data has also contributed to better understanding the knowledge and skills of cancer clinical trials nurses in Australia and development of postgraduate course in clinical trials at the University of Sydney
Nagel et al	2010	USA	Quantitative-questionnaire	To describe the roles and responsibilities of the CRN in paediatric oncology.	N=85	Clinical specialisation of RNs has increased significantly and nurses are responsible for performing different roles that contribute to the success of CT
Habermann et al	2010	USA	Quantitative-	To describe	N=266	The study demonstrates the need to expand

Author	Year	Country	Method	Description	Sample	Conclusion
			questionnaire	research coordinators' experiences with scientific misconduct in their clinical environment.		definitions of scientific misconduct beyond fabrication, falsification, and plagiarism to include other practices. The importance of the ethical climate in the institution in ensuring a safe environment to report and an environment where evidence is reviewed cannot be overlooked.
Catania et al	2008	Italy	Quantitative-questionnaire	An assessment of the research nurse role in Italy	N=30	The new validated survey instrument will be used in a national survey aimed at assessing the role of the Italian clinical trials research nurse and support to delineate the framework of the general competencies required for basic and advanced levels of practice for nurses involved in clinical trials research
Jeong et al	2007	S Korea	Quantitative-questionnaire	To determine the roles, proficiency and qualification of CRN in South Korea	N=150 PI=71 CRN=79	Communication and human relationship are the most important skills for CRNs with minimum Bachelors degree and one year experience in CT.
Cantini and Ells	2007	Canada	Quantitative-questionnaire	To elicit information about the practice CTN in the informed consent process	N=95	Results of the study point to the need for standard ethical and practical guidelines with respect to the role of the CTN in the informed consent process
Spilsbury et al	2007	UK	Qualitative - focus group	To explore the scope and potential contribution of the CRN role to clinical trials research of nursing specific topic	N=9	The study reveals challenges associated with training and management of CRNs and contributions to nursing specific trials.

Author	Year	Country	Method	Description	Sample	Conclusion
Gwede et al	2005	USA	Quantitative-questionnaire	To assess burnout among CRC and to determine which personal and job related factors are associated with burnouts	N=252	Burnout is prevalent in CRC
Fisher	2006	USA	Qualitative-interviews	Examination of the role RC in the conduct of contract research in USA	N=57	Study demonstrates how clinical trial coordinators' focus on ethics is a response to their role conflict and an attempt to reinsert individualised care in to the context of research.
Easter et al	2006	USA	Qualitative-interviews	To investigate how the researchers and subjects who participate in CT understand the presence of care in research	N=82 CRN=18 Patient=45 PI=19	Researchers and subjects perceived many kinds of care in researcher roles and relationships and often these relationships were both 'different and better'
Rickard et al	2006	Australia and New Zealand	Quantitative - questionnaire	To ascertain demographics, education, employment history, job structure and role content	N= 49	The study indicated that most research coordinators were highly qualified and experienced nurses who undertake pharmaceutical trials, multi centre trials, medical and nursing researchers, audits, data management and their own research.
Hill and MacArthur	2006	UK				
Study 1	2002		Qualitative-questionnaire	To identify and elicit information	N=72	Research nurses need to be supported through educational means, their contractual agreement

Author	Year	Country	Method	Description	Sample	Conclusion
				in regards to human resources issues		clarified, better supported and supported in developing nurse led research.
Study 2	2003		Questionnaire and focus group	To explore experiences and knowledge specifically professional development and support issues	N=50	
Simpson	2006	UK	Quantitative-questionnaire	To identify the research roles provided by nurses and midwives and to understand their professional development needs	N=116	
Deave	2005	UK	Qualitative - documentary analysis	To identify whether knowledge of research is stated in employment advertisements	N=82 in 2002 N=75 in 2005	Knowledge or experience of research not usually a requirement for the research nurse post
Rico-Villadermoros et al	2004	Spain	Qualitative-questionnaire	Determine standard tasks performed by CRC in oncology clinical trials research	N=41	CRC play a key role in the implementation of oncology clinical trials research which goes far beyond data collection and administrative duties and directly contributes to the gathering of quality data.
Ehrenberger and Lilington	2004	USA and Canada	Questionnaire and focus group	To identify the significant dimension of the	N=40	The CTNQ has acceptable content validity, internal consistency, and stability reliability and is a promising tool for the assessment of research nurse

Author	Year	Country	Method	Description	Sample	Conclusion
				role of CRN and to construct a reliable and valid survey instrument to reflect these dimensions		role.
Davis et al	2002	USA	Qualitative-Focus group	To ascertain the role of study coordinators	N=45	The study finds that study coordinators face challenging issues related to trial participants and require research ethical training
Loh et al	2002	Australia	Qualitative-Focus group	To explore the role of the data manager and to determine the similarities and challenges of their role with that of the physicians in obtaining consent	N=21 Mix Health Prof	Issues raised by data managers have important implications for successful conduct of clinical trials research, particularly the need for an integrated, multidisciplinary approach at all levels of the informed consent process.
Grunfeld et al	2002	Canada	Qualitative-Focus group	To identify barriers and facilitators to the accrual of patients with cancer regarding clinical trial entry, specifically from the CRA perspective	N=29	Further research into the role of CRA impacting on the accrual of patients needed
Mueller	2001	USA	Qualitative-Interviews	To investigate the role, career and work experiences of nurse trial coordinators	N=38	Nurse trial coordinators view their position as part medicine and part nursing. Nursing needs to show empirically if the role is exclusive to nursing
Xanthos et al	1998	USA	Qualitative-	To delineate the	N=23	Role of nurses in clinical trial identified, needs

Author	Year	Country	Method	Description	Sample	Conclusion
			questionnaire	nurses' role in clinical trials research in terms of their job description		educational and organisational support in future
Aarigo et al	1994	15 European Countries	Qualitative-questionnaire	To identify nurses involved in clinical trials research and document their specific needs	N=312	Nurses involved in clinical trials research need to be involved in clinical trial protocol development, networking with other nurses working on the trials and participate in clinical trial meetings.
Ahern et al	1993	USA	Quantitative-questionnaire	To document the different activities for which the trial coordinator assumed responsibility	N=21	Study identified the need to develop a means to define characteristics, background and training appropriate for candidates in this position