Guidelines for clinical research nurses about their self-leadership role in nursing practice at nursing units in the southern suburbs of Cape Town, Western Cape

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ABSTRACT

Clinical research nurses are at the frontline of clinical research. They act as nurse leaders in the area of patient-orientated research. This leadership role requires that they work independently with limited support from other nurses. The nursing practice of clinical research nurses' associates patient care with research protocols, administration duties, management responsibilities, and role specific authority. At hospitals in the Western Cape, clinical research nurses support principal investigators in the conducting of clinical research.

It was unclear how clinical research nurses in nursing units in southern suburbs, Cape Town, Western Cape Province experienced their self-leadership role in nursing practice. The aim of the study was to explore and describe the experiences of clinical research nurses' self-leadership role in nursing practice in nursing units in the southern suburbs of Cape Town, Western Cape. In this study; a phenomenological, exploratory, descriptive, and contextual design was followed. The population consisted of all the clinical research nurses (n = 22) at Western Cape hospitals and health care institutions in the southern suburbs. Purposive sampling was applied according to selection criteria. Unstructured individual interviews were conducted until data saturation occurred. These interviews took place at a private office in the southern suburbs of the Cape Town and lasted between 45 minutes and an hour. Observation and field notes were taken during the interviews. Data was analysed by using open coding and data triangulation. The researcher applied Lincoln and Guba's (1985) model of trustworthiness. Four themes and twenty one categories emerged from the data analysis. The findings emphasised that the clinical research nurses' experienced their self-leadership role in nursing as an evolutionary process. The evolutionary role required that they needed to develop strategies with the aim of surviving the initial tedious and daunting phase that facilitated the development of skills needed for collaborative partnerships with stakeholders. As her general confidence increased, the clinical research nurse would be able to recognise her professional attributes and use self-leadership behaviour to enhance her daily practice. Appropriate self-leadership behaviour would assist the clinical research nurse to successfully navigate the complex, dynamic clinical research environment.

Guidelines were developed from the four themes that were the result of the data analysis; namely the initial tedious and daunting phase, working in pursuit of collaborative action, personal traits of the clinical research nurse, and self-leadership behaviour.

The UWC Higher Degree Committee at the Faculty of Community and Health Sciences and the Senate Research Committee respectively approved this research project. No risks were anticipated for participants in the study.

Keywords: Clinical research nurse, self-leadership, nursing units, interviews, Professional Nurse, nursing practice,experiences, guidelines

DECLARATION

I declare that ***Guidelines for clinical research nurses about their self-leadership role in nursing practice at nursing units in the southern suburbs of Cape Town, Western Cape*** is my own work, that it has not been submitted before for any degree or examination at any other university, and that all the sources I have used or quoted are indicated and acknowledged in the format complete references.

CKReddy

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LIST OF ACRONYMS

AGA	Achievement goal approach
CRA	Clinical research associate
CRO	Contract Research Organisation
DOH	Department of Health
ECG	Electrocardiogram
ECRF	Electronic case report forms
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GP	General practitioner
HWSETA	Health and Welfare Sector Education and Training Authority
ICH -GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
ICN	International Code of Nurses
ICU	Intensive Care Unit
LGO	Learning goal orientation
MRC	Medical Research Council
MRI	Magnetic resonance imaging
NHRC	National Health Research Committee
NHREC	National Health Research Ethics Council

NHS	National Health Scheme
NQF	National Qualifications Framework
PGO	Performance goal orientation
PHC	Public Health Care
PI	Principal investigator
RCT	Randomised Control Trial
REC	Research Ethics Committee
SACRA	South African Clinical Research Association
SA GCP	South African Guidelines for Good Clinical Practice
SANC	South African Nursing Council
SAQA	South African Qualifications Authority
SOP	Standard Operating Procedures
UK	United Kingdom
WHO	World Health Organization

CHAPTER 1
INTRODUCTION

1.1 INTRODUCTION

Patient-orientated research involves the inclusion of patients in a hospital environment and can be described as clinical research (National Institute of Health, 2009, p. 26) Patient-orientated research focuses on the study of human diseases, therapies or interventions for disease, new technology related to disease, epidemiological and behavioural studies, health services research, and clinical trials (National Institute of Health, 2009, p. 26). It has become common practice for nurses to be recruited to and / or to seek careers external to the traditional domain of hospital-based work; one of these areas is clinical research (Mueller & Mamo, 2002, p. 33). Literature reviews conducted by Mueller (2001) and by Raja-Jones (2002) reveals a role shift from the physician to coordinators of trials. Physicians for clinical research appoint nurses to coordinate their studies. The clinical research nurse in South Africa is involved in research in a variety of clinical settings.

Research has only recently established what nurses, who are involved in patient-orientated research in the form of clinical trials, should perceive about their nursing practice as part of the multidisciplinary team (Castro, Bevans, Miller-Davis, Cusack, Loscalzo, Matlock, Mayberry, Tondreau, Walsh & Hastings, 2011, p. 77). While the emphasis on high quality ethical research grows and the pace of clinical research accelerates, nurse leaders will be expected to evaluate their resources to accommodate more research related activities of the clinical research nurse (Castro *et al.*, 2011, p. 73; Gibbs & Lowton, 2012, p. 37). This phenomenon is also happening in the South African context (Siegfried, Volmink & Dhansay, 2010, p. 523).

The National Health Summit (2011) sets priorities for clinical research (Mayosi, Mekwa, Blackburn, Coovadia, Friedman, Jeenah, Madela-Mntla, Magwaza, Makatini, Mkhize, Mokgatle-Makwakwa, Mokwena, Nevhutalu & Paruk, 2011, p. 1). A new funding approach has been adopted that is directed at developing the health research infrastructure of academic health complexes. The priority identifies the creation of clinical research centres at academic health complexes based on a primary health care (PHC) approach and by means of a competitive process. This competitive process means that it has now become imperative that the self-leadership role of clinical research nurses is explored to ensure the viability of

research centres (Fokazi, 2012). It has been suggested that this new strategic programme should also be co-ordinated by the National Health Research Committee (NHRC) and implemented by the Medical Research Council (MRC) and other related science councils. Clinical research nurses form an essential part of these clinical research centres and it is necessary to document their self-leadership role in nursing practice and to establish their management processes (Mayosi *et al*., 2011, p. 1).

The function of the clinical research nurse and the formalisation of the role for nurses in clinical research by nursing leaders are a fairly recent development (Gibbs & Lowton, 2012, p. 37). The clinical research nurse, in collaboration with the principal investigator, is responsible for recruiting patients, implementing protocols, monitoring either positive or negative side effects, evaluating outcomes, advocating on behalf of patients, and interpreting clinical data for patients (Castro *et al.*, 2011; Sadler, Lantz, Fullerton & Dault, 1999, p. 107). Often, the principal investigator delegates many of these tasks to the clinical research nurse (Gibbs & Lowton, 2012, p. 38). Practically, it means that the clinical research nurse becomes *solely* responsible for directing these tasks. These tasks require self-leadership of clinical research nurses.

1.2 BACKGROUND

Clinical research is considered to be the golden standard of patient-orientated research and will remain the most influential research in future. Burgess and Sulzer (2010, p. 402) cite Richardson (2009) who states that the South African Clinical Research Association (SACRA) estimates that in 2008 approximately R2.2 billion was generated by conducting internationally sponsored Randomised Control Trials(RCTs). All clinical trials in South Africa are subject to the scrutiny of an ethical review process by an accredited ethics committee (Department of Health, 2006, p. 10). In turn, this committee reports to the National Health Research Ethics Council (NHREC) (Department of Health, 2006, p. 11). This ethical review process certifies that a particular research study subscribes to the guidelines identified in the South African Guidelines of Good Clinical Practice (2006), The Declaration of Helsinki (2008), as well as the International Conference on Harmonisation Guidelines for Good Clinical Practice (Hutchinson, 2008). The clinical research nurse must, therefore, exercise self-leadership to accountably adhere to these guidelines. Self-leadership allows her to use her authority as a professional nurse to fulfil her role in nursing practice. The Nursing Act Chapter 2, Section 30.1 (South African Nursing Council, 2005, p. 25) states

that “a professional nurse is a person who is qualified and competent to independently practise comprehensive nursing in the manner and to the level prescribed and who is capable of assuming responsibility and accountability for such practice”.

The Declaration of Helsinki adopted in 1964 by the World Medical Association (2008) serves as the founding principles on which patient-orientated research is built. It is essential, however, that these principles include a means of implementation (World Medical Association, 2008, p. 1). The International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice (Hutchinson, 2008) serves as the rule book, since it is the source that enables clinical researchers to make the concepts of the Declaration of Helsinki practicable in the real world. The South African Guidelines for Good Clinical Practice, Department of Health (2006, p. 2) provides a basis for all clinical trial research currently conducted in South Africa and serves to ensure a standardised and ethical approach to clinical trial activities in South Africa. Research has only recently established that nurses who are involved in patient-orientated research in the form of clinical trials should be part of the multidisciplinary team in nursing practice (Castro *et al.*, 2011, p. 77). It is not currently the case.

1.3 SELF LEADERSHIP

Self-leadership is best described as the process of influencing oneself to achieve the self-direction and self-motivation that are necessary to achieve identified goals (Neck & Houghton, 2007, p. 271). Self-leadership provides for self-regulation, self-control, and intrinsic motivation (Andressen, Konradt & Neck, 2012, p. 70). Influencing oneself means that self-direction and self-motivation allow an individual to perform in a desirable way. Recently, the concept of self-leadership has been introduced – at least partly – to distinguish between different levels of self-influence and to provide a broader, more encompassing perspective that includes, but looks beyond, a primarily discipline and a behaviourally grounded self-management process (Stewart, Courtright & Manz, 2011, p. 188). In order to achieve this desirable performance; specific behavioural, natural, cognitive, and constructive thought pattern strategies are necessary (Neck & Houghton, 2007, p. 271). These strategies imply that both extrinsic and intrinsic factors influence an individual, with an emphasis on intrinsic factors (Stewart, Courtright & Manz, 2011, p. 190).

Gibbs and Lowton (2012, p. 38) report that clinical research nurses assume the following responsibilities and skills: "screening, recruitment and obtaining informed consent from patients and / or relatives; administration of the intervention being studied; monitoring participants and performing some laboratory work, collecting data, and reporting any adverse events; and general management of the trial, including maintenance of study files and resolving data queries". In order to accomplish the aforementioned responsibilities, the clinical research nurse must use extrinsic and intrinsic factors to influence the outcomes of her endeavours. In this study, the researcher explored the experiences of clinical research nurses and their self-leadership as part of the domain of clinical research. Self-leadership encompasses intrinsically behaviour-focused strategies; such as self-observation, self-goal setting, self-reward, self-punishment, and self-correction (Neck & Houghton, 2007, p. 271).

Strategies of self-leadership involve building features into a task that make the task more pleasant to perform (Stewart, Courtright & Manz, 2011, p. 188). For a clinical research nurse, it may involve ensuring that when she needs to resolve queries, it requires her interaction with other members of the multidisciplinary team with whom she has a good relationship while at the same time she changes negative perceptions about clinical research (Neck & Manz, 2007). Self-leadership provides an individual with a sense of competence and self-motivation (Andressen, *et al.*, 2012, p. 70). These intrinsic factors may allow the clinical research nurse to continue in her often demanding job that in turn energises performance-enhancing task-related behaviour.

Furthermore, self-leadership includes constructive thought pattern strategies that identify and replace dysfunctional beliefs and create new thought patterns or serve to change existing thought patterns into more positive ones (Neck & Manz, 2007). An area in the nursing environment where constructive thought patterns are needed is e.g. the communication between the clinical research nurse and line management in the unit.

The idea of influencing oneself means that the power, through self-responsibility and knowledge rests in the hands of an individual. Considerable research has revealed positive effects of self-leadership on work-related outcomes and managerial analysts have linked the construct of empowerment to organisational effectiveness, team building, and group cohesion (Stewart, Courtright & Manz, 2011). According to Stewart, Courtright and Manz (2011, p. 189), unlike traditional management where members have little autonomy and limited decision-making authority, individuals who are "self-managing" or "self-leading" have

authority over work processes and are allowed to regulate their own behaviour. Exploring the clinical research nurses' self-leadership in nursing practice serves to increase the available body of knowledge about self-leadership of clinical research nurses.

1.4 PROBLEM STATEMENT

Nurses have long been active in the implementation of medical research (Bevans, Hastings, Wehrlen, Cusack, Matlock, Miller-Davis, Tondreau, Walsh & Wallen, 2011, p. 421). The researcher observed an increase in the trend that physicians and surgeons co-opt independent practitioners (such as clinical research nurses) to assist them with conducting patient-centred research (clinical studies) in the southern suburbs of Cape Town. The rise in the number of clinical research nurses can be linked to research that indicates an annual increase in the number of published trials with their origins in Sub-Saharan Africa (Burgess & Sulzer, 2010; Isaakidis & Ioannidis, 2003). Clinical research refers to wound care, new drug therapies, unique biomedical devices, and comparative studies. It is implied then that the care of patients is often provided in a general nursing unit, where clinical research nurses conduct studies. These nurses are not always viewed as part of the multidisciplinary team but as independent practitioners (Gibbs & Lowton, 2012). Clinical research nurses report to their principal investigators who in turn report to research ethics committees and sponsors. These nurses mainly influence themselves to conduct research; and take the necessary decisions during the execution of their tasks to obtain the desired outcomes for the clinical trial and the patient.

Literature confirms that clinical research nurses must direct themselves during clinical studies in practice (Burgess & Sulzer, 2010, p. 402). During the self-leadership role of clinical research nurses, they enhance patient recruitment, informed consent, patient retention, appropriate data collection, and ensure the success of many clinical trials. It was unclear how clinical research nurses experience their self-leadership during clinical research in nursing practice. From the problem statement, the following questions were asked:

- What are the experiences of clinical research nurses in relation to their self-leadership role during clinical research in nursing practice?
- How could clinical research nurses lead themselves in nursing practice?

1.5 AIM OF THE STUDY

The aim of the study was to develop guidelines for clinical research nurses about their self-leadership role in nursing practice at general nursing units in the Western Cape.

1.6 OBJECTIVES

The objectives of this study were to:

- explore and describe the experiences of the clinical research nurse about their self-leadership role during clinical research in nursing practice; and
- develop guidelines for clinical research nurses about their self-leadership role in nursing practice.

1.7 SIGNIFICANCE OF THE STUDY

No research had been conducted in the South African setting about the role of the clinical research nurse. The clinical research nurse is needed to assist with the continual growth of clinical research in health care services in South Africa (Burgess & Sulzer, 2010; Mayosi, 2011). It was necessary to conduct a study that explored the phenomenon of clinical research nurses who led themselves while supporting the principal investigator during clinical research.

1.8 DEFINITION OF TERMS

Professional nurse

The Nursing Act (South African Nursing Act No 33 of 2005, 2005) describes a professional nurse as a person who is qualified and competent to independently practise comprehensive nursing in the manner and to the level prescribed and who is capable of assuming responsibility and accountability for such practice.

Clinical research nurse

In this study, a clinical research nurse refers to any professional nurse who is employed by a principal investigator to undertake research within the clinical environment. A clinical research nurse is defined as a professional nurse who is employed at research sites to facilitate and conduct any phase of a research trial (Spilsbury, Petherick, Cullum, Nelson,

Nixon & Mason, 2008, p. 551). A clinical research nurse is a professional nurse who is enabled to make important contributions to research integrity, patient care, care coordination, and human subjects' protection (Bevans *et al*., 2011, p. 427).

Nursing practice

Nursing is defined as the autonomous and collaborative care of individuals of all ages, families, groups, and communities, whether either sick or well and in all settings. It includes the promotion of health, the prevention of illness, and the care of ill, disabled and, dying people (WHO, 2012). The practice of nursing involves the implementation of this aforementioned definition.

Experience

The Oxford Dictionary (Soanes & Stevenson, 2005) describes both the *"noun"* and the *"verb"* of the word experience. This research study used both descriptions. In its *"noun"* form, an experience can be defined as: "the process of getting knowledge from doing, seeing, or feeling things*"*. In its *"verb"* form, experience can be defined as: "something that happens to you, or you feel it*"*.

Guidelines

Guidelines are defined as rules, principles, or bits of advice (Soanes & Stevenson, 2005).

Self-leadership

Self-leadership is the process of influencing and using one's own power, e.g. knowledge to achieve the self-direction and self-motivation necessary to perform tasks (Neck & Houghton, 2007, p. 271).

1.9 DESIGN

A phenomenological, exploratory, descriptive, contextual design was followed. Qualitative research is described as an investigation of phenomena typically in an in-depth and holistic fashion (Polit & Beck, 2012, p. 739). A phenomenological descriptive design enabled the researcher to provide an account of how clinical research nurses viewed their self-leadership role and to emphasise the essence of what self-leadership is for a nurse in clinical research. This research study was exploratory in nature. The clinical research nurses' experiences of

their self-leadership role in nursing practice were studied. Description implies an accurate account of the phenomena that are being studied (Polit & Beck, 2012, p. 725).

Context is best described as the dimensions that define a study. The context had been pre-determined by the researcher, based on addressing the research priorities and recommendations that were identified in the National Health Summit 2011 (Mayosi *et al*., 2011, p .5). The study was undertaken with clinical research nurses who were working in nursing units in the southern suburbs of Cape Town in the Western Cape. (The southern suburbs refer to the following areas in Cape Town: Rondebosch, Claremont, Plumstead, Ottery, Wynberg, Newlands, Constantia, Bishops Court, Pinelands, and Observatory.)

1.10 POPULATION AND SAMPLE

A population is the entire set of individuals who have some characteristics in common (Polit & Beck, 2012, p. 738). An accessible population was used from the district of the southern suburbs of Cape Town (n = 22). Brink, Van der Walt and Van Rensburg (2012, p. 208) define an accessible population "as the group of people that is (sic) available to the researcher for a particular study". Participants' names were obtained from a Clinical Research Organisation in the Western Cape with a register of all clinical research nurses, that was based in the southern suburbs of Cape Town. The information provided was used to identify the accessible population.

A form of non-probability sampling known as purposive sampling was used. This type of sampling is based on the judgement of the researcher (Brink, *et al*., 2012, p. 141). The aim of this research project was to choose individuals who would most benefit from the study; hence purposive sampling was used. In a research study, eligibility criteria determine the specific attributes of the target population; this in turn determined how participants are selected for inclusion in a study (Polit & Beck, 2012, p. 726). The criteria identified for this study are outlined in Chapter 2. Seven (n = 7) individual unstructured interviews were conducted until themes that evolved became repetitive and data saturation was reached.

1.11 DATA COLLECTION

In order to collect data, the researcher conducted unstructured interviews with the study participants. An un-structured interview technique takes into consideration the nature of the research, time constraints, and the need to obtain high quality data. Probing statements were

used to elicit more detailed information (Polit & Beck, 2012, p. 537). The data collection process began in February 2013 and continued until data saturation occurred. Participants were initially asked to come to the offices of 3 Degree Clinical Research and Consulting, which was a private location where the interviews would have been conducted. However, due to the time constraints of participants, a private venue at one of the research sites that was convenient for both researcher and participant was used. Privacy meant that the researcher could undertake private voice recordings of the face-to-face interviews. The interviews lasted approximately 45 minutes to an hour. During each interview, the researcher also took field notes that allowed for a more trustworthy data collection process (Polit & Beck, 2012, p. 543). Data was collected until data saturation was achieved. This meant that emerging themes were developed until no additional information was provided (Brink, *et al*., 2012, p. 141).

1.12 DATA ANALYSIS

Data analysis was conducted concurrently with data collection. To ensure appropriate analysis of the data, the researcher used recognised data management and data organisation steps. Transcription of the interviews took place in order to validly reflect on the interview experience from the voice recording. Open coding was used, defined as the first level of coding that required basic descriptive coding of the transcribed content (Polit & Beck, 2012, p. 736). Data analysis involved data reduction and subsequent interpretation by using a scheme (Tesch, 1990, p. 141-145). Data triangulation of transcripts and field notes was conducted. The researcher followed the principles of Streubert (1991) and some steps of coding outlined by Bruce (2010), (Bruce & Klopper, 2010, Streubert & Carpenter, 2011). Transcripts were read to gain an overall general view (Bruce & Klopper, 2010). Secondly, a sense of the underlying meaning of the transcripts was gaged. That list was then reduced to groups of similar topics. The codes were transposed into themes.

1.13 DEVELOPMENT OF GUIDELINES

The method used by Muller (2006, pp. 204 – 205) to develop guidelines was applied during this research study. The themes obtained from the data analysis served as a point of departure for formulating the main guidelines. Each guideline was motivated by means of a rationale. Based on the findings of the study, specifically required actions for each guideline were described. The researcher requested two experts in the field of clinical research working with clinical research nurses, to validate the guidelines by using the evaluation criteria of Chinn

and Kramer (2008) that referred to clarity, simplicity, generality, accessibility, and the importance of the guidelines. The experts did not recommend any changes to the guidelines.

1.14 TRUSTWORTHINESS

The model for trustworthiness of Guba (1981) in Lincoln and Guba (1985, p. 219) was maintained. The model describes the criteria of credibility, dependability, confirmability, transferability, and authenticity. Trustworthiness is described in Chapter 2.

1.15 ETHICAL CONSIDERATIONS

Obtaining permission and informed consent

The Research Senate Committee of a university in the Western Cape approved the research proposal (Ethical clearance number 12/10/24). The researcher obtained permission from an institute to use on of its private rooms for conducting the interviews. Only after approval had been granted, did any study related activities begin. Written informed consent was obtained from participants, an information sheet provided, and the researcher answered questions from participants in relation to the research process. All participants in a research study are required to sign an informed consent form (Bhattacherjee, 2012, p. 147). The informed consent document was emailed to the participants prior to the interview. That was done in order to give the participants the opportunity to review the document. The participants' right to withdraw consent, as well as the right not to participate were discussed in the consent document; the researcher also had a verbal discussion with each participant about consent before an interview had taken place (Bhattacherjee, 2012, p. 147).

Right to withdraw

The participants were all informed that their participation in this study was completely voluntary and that at any stage in the research process they had the right to withdraw. That was explained not only in the informed consent document, but also verbally prior to the commencement of interviews. In one instance, the researcher had received a consent document and confirmed an interview time with one of the possible participants. That participant declined to participate on the grounds that she was uncomfortable with the interview being voice recorded. As a result, that participant was excluded from the study.

Right to self-determination

The ethical principle of respect for persons was adhered to by ensuring that the research participants retained their right to self-determination. The researcher respected the rights of the individuals to decide whether or not to participate in the study, without any risk of penalty or prejudicial treatment (Brink, *et al*., 2012, p. 35). The participants were all informed that their participation in this study was completely voluntary and that at any stage in the research process they had the right to withdraw.

Right to privacy

Privacy means that participants determine the environment and circumstances under which personal information is shared (Brink, *et al*., 2012, p. 37). No data was collected without the written consent of participants. Principle 11 of The South African Guidelines of Good Clinical Practice (2006) states:

> "*The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s)*."

Since that was the standard for the conduct and practice of clinical research, the researcher chose to apply the same rigor to the conduct of her research.

Right to autonomy and confidentiality

To protect participants' interests and future well-being, their identity must be protected in a research study. This is done by using the dual principles of anonymity and confidentiality (Bhattacherjee, 2012, p. 147). During this study, the researcher did not share any information gathered from the interviews without the authorisation of the participants.

Anonymity implies that a researcher or readers of the final research report or paper should not be able to identify a given response with any specific participant (Bhattacherjee, 2012, p. 147). While the researcher adhered to this principle, it was impossible to maintain anonymity between the researcher and the participants but the researcher did implement confidentiality procedures (Polit & Beck, 2012, p. 162).

Given that qualitative studies often contain rich descriptions of study participants, confidentiality breaches via deductive disclosure are of particular concern to qualitative researchers. Hence during the analysis phase, the researcher faced a conflict between conveying detailed, accurate accounts of the dialogue and protecting the identities of the individuals who participated in the research project (Kaiser, 2009, p. 1). During the analysis, the researcher cautiously took time and care to extract participant transcripts in such a way that only the researcher could identify a participant's responses and aimed at not disclosing participants' identity in any report, paper, or public forum. For the purposes of this research study, the researcher maintained confidentiality and in the written report she used unique participant identity codes to identify certain statements linked to a participant. Those codes had no meaning to anyone but the researcher.

The data would be kept in a locked cupboard by the researcher for five years after publication of the results before it is destroyed (Polit & Beck, 2012, p. 163).

Right to protection from discomfort and harm

During research that involves human beings, a researcher ought to mitigate harm and discomfort, since it is vitally important that the participants are protected from unnecessary risks of harm or discomfort (Polit, 2012, p. 153). Interviews were held in a private environment and no participants had emotional responses during the interview process, therefore, counselling services were not needed during this study.

1.16 CONCLUSION

This chapter introduces the research study conducted.

CHAPTER 2
RESEARCH METHODOLOGY

2.1 INTRODUCTION

This chapter discusses the research methodology used in this study. A descriptive phenomenological qualitative research approach was identified as the directive approach for this research project. The research design, population sampling, data collection and data analysis structure of this study are covered in this chapter.

Research methodology is the planning, structuring, and execution of research (Uys, 1991, p. 2). It is concerned with the ideas and principles on which procedures are based (Holloway & Wheeler, 2010, p. 42). Methodology in this study illustrated the decisions that the researcher had taken with respect to the formulation of a problem, the research design, and the research strategies and techniques (Uys, 1991, p. 2). The focus of this study was to explore and describe how clinical research nurses experienced their nursing practice self-leadership roles in nursing units.

The research methodology allowed the researcher to look at the logic behind the methods used in the context of the research study. Literature describes the importance of methodology by stating that it is a coherent group of methods that complement one another and that have the ability to deliver data and findings that would reflect the research question and suit the research process (Henning, Van Rensburg & Smit, 2004, p. 36).

2.2 STUDY DESIGN

This study kept to the parameters of phenomenological qualitative research. By placing this study in the framework of phenomenological qualitative research, the researcher had to ensure congruence between methodology and methods, adopt strategies to establish rigor, and use an analytic lens through which the data was examined (Caelli, Ray & Mill, 2003, p. 5). A phenomenological, exploratory, descriptive, contextual design was followed.

2.2.1 Qualitative research

Qualitative research is a situated activity that locates the researcher in the world, it requires a multi-method approach, and through a set of interpretive material practices makes the world visible. It makes a naturalistic approach to a researcher's subject matter possible (Denzin &

Lincoln, 2011, p. 3). This form of research permits the exploration of the different dimensions of the social world. This includes the texture and weave of everyday life; the understandings, experiences, and imaginings of the study participants; institutions, discourses, or relationships; and the significance of the meanings that they generate (Mason, 2002, p. 1). These different dimensions enabled the researcher to build a holistic, largely narrative, description that served to understand the phenomenon (Astalin, 2013, p. 118).

The context of an individual's experiences is unique. The researcher used the 'emic' perspective to explore the ideas and perceptions that were unique to the participants (Streubert & Carpenter, 2011, p. 20). This perspective made it possible to gain an in-depth insight into the knowledge of the participants' reality and unique context. It did not aim at generalising the results to the broader population but sought to generate new knowledge and understanding (Bless, Higson-Smith & Sithole, 2013, p. 162). When the researcher considered whether to use a quantitative or qualitative research design, two essential questions were considered:

- What is the aim of the research?
- What type of data will achieve this aim? (Terre Blanche, Terre Blanche, Durheim & Painter 2006, p. 45).

Quantitative research is defined as research that makes sense in situations where we know in advance what the important variables are. It enables a researcher to devise reasonable ways of controlling or measuring outcomes (Terre Blanche *et al*., 2006, p. 275). Intuitively, one conducts a quantitative study when enough is known about the issue in order to ensure the validity of the research findings. That was not the case with this study. Quantitative data is collected according to a very specific set of steps with the purpos of remaining objective and neutral (Bless *et al*., 2013, p. 16). The technical, fixed design of a quantitative study would have been too restrictive and hence unsuited to the exploratory nature of this research topic (Terre Blanche *et al*., 2006, p. 36).

A qualitative research approach was chosen for this study, since it lent itself to achieving the aims of this research. The clinical research nurse in South Africa and her nursing practice have not been studied; as such, there are a multitude of questions to ask. But how does one go about asking the right questions? In qualitative research, the researcher becomes involved and immersed in the phenomenon and from this immersion seeks to develop knowledge (Caelli *et*

al., 2003, p. 2). As little was known about how clinical research nurses experienced their self-leadership role in nursing practice in the Western Cape Province of South Africa, the researcher felt it was important to choose a design that would allow the voice and the lived experience of the clinical research nurse to be heard. The designs proposed by qualitative researchers are more open, fluid, and changeable; it is with this particular tool that the researcher had decided to embark upon this study (Terre Blanche *et al.*, 2006, p. 25).

The researcher followed a qualitative design, since:

- Qualitative research was best suited for this study;
- There was a commitment to identifying an approach that supported the phenomenon studied while taking the participants points of view into account;
- The inquiry was conducted in such a way that limited disruption of the natural context of the phenomena of interest occurred;
- It acknowledged the participation of the researcher in the process; and
- Allowed for reporting of data in a literary style with supporting participants' comments (Streubert & Carpenter, 2011, p. 20).

2.2.2 Exploratory research

Exploratory research is defined as research conducted to gain insight into or knowledge about a particular phenomenon of interest (Kowalczyk, 2014). An exploratory method was used in this study to gain insight, discover new ideas, and increase knowledge in the area of how clinical research nurses experienced their self-leadership role in nursing (Creswell, 2014, p. 29). The advantage of exploratory qualitative research is the use of open-ended and probing questions that provides participants with an opportunity to respond in their own words rather than expecting them to choose from fixed responses. Open-ended questions evoke responses that are meaningful and culturally salient to the participant, unanticipated by the researcher, as well as rich and explanatory in nature (Family Health International, 2005, p. 4)

2.2.3 Descriptive research

The aim of descriptive research is to describe rather than to explain a phenomenon (Bless *et al*., 2013, p. 390). A descriptive analysis seeks to explore the essence of a phenomenon as faithfully as possible. In a phenomenological sense, descriptive research allows a researcher to extract and emphasise essential components of the specific lived experiences of a group of

people, which otherwise might not have been identified by the individuals themselves (Lopez & Willis, 2004, p. 727). It calls for exploration of phenomena through direct interactions and requires that one has the ability to set aside preconceptions (Wojnar & Swanson, 2007, p. 174).

2.2.4 Contextual research

Contextual research means that the study focuses on specific events in natural settings and that allows a researcher to capture and understand the meanings of such experiences (Zhou, 2010, p. 313). For this particular study, the context was the clinical research nurses' experiences in general nursing units at public and private hospitals, where the clinical research nurse conducted her nursing research practice.

2.2.5 Phenomenological research

Phenomenology is used by numerous qualitative nurse researchers (Lambert & Lambert, 2010, p. 183). Essentially, there are two schools of phenomenology, namely descriptive (Husserlian) and interpretive phenomenology (Heidegger) (Tuohy, Cooney, Dowling, Murphy & Sixsmith, 2013, p. 17). There are inherent differences between the different philosophical perspectives and the researcher noted and took cognisance of these differences during the course of this research study. Cohen and Omery (1994) and Sarantakos (2005) as cited in Dowling and Cooney (2012, p. 23) purport that phenomenological reduction or bracketing is the distinguishing characteristic of Husserlian phenomenology.

Descriptive phenomenology is the direct investigation, analysis, and description of the phenomena under study. It needs to be as free as possible from either preconceived expectations or presuppositions (Omery, 1983, p. 52). Nurse researchers often describe their research as either of a Husserlian or Heideggerian phenomenological nature when they are neither (Dowling & Cooney, 2012, p. 26). To avoid such confusion, the researcher acknowledged that whilst the Husserlian school of thought underpinned this study, ultimately there was no single way of carrying out a phenomenological study; therefore, this study might contain aspects that are not strictly Husserlian in nature (Dowling & Cooney, 2012, p. 27).

2.2.6 Definition of phenomenological research

The phenomenological method is an inductive, descriptive research method (Omery, 1983, p. 50). Phenomenology is a science that purposefully describes a particular phenomenon or the appearance of things as lived experiences (Streubert & Carpenter, 2011, p. 73). This approach was the most appropriate to the aim of this study.

2.2.7 Advantages of phenomenological research

Nursing encourages detailed attention to the care of people as human beings and grounds its practice in a holistic belief system that nurses care for the body, mind, and spirit. As such, this study offered the same respect to those who practice nursing, i.e. clinical research nurses. Holistic care and the avoidance of reductionism are at the centre of professional nursing practice (Streubert & Carpenter, 2011, p. 87). This study built on that philosophy and, therefore, applied phenomenological inquiry. Phenomenological inquiry requires that the integrated whole be explored and this advantage is paramount to a study that seeks to inform nursing practice (Streubert & Carpenter, 2011, p. 87).

2.2.8 Advocating for the use of phenomenological research

If one desires the research to be a reflection of the experiences of the phenomenon under study, it is anticipated that a phenomenological approach would have achieved this objective. When a phenomenological study is conducted, the inter-subjective reality and the autobiographical accounts keep the phenomenon alive and illuminated. That enabled the researcher to present a description of the phenomenon in accurate and vivid terms (Salmon, 2012, p. 5).

Procedural principles:

The researcher followed the principles of Streubert (1991) in Streubert and Carpenter (2011, p. 80) and Bruce and Klopper (2010):

1. Bracketing the researcher's presuppositions;
2. Interviewing participants in an unfamiliar setting;
3. Carefully reading the interview transcripts to obtain a general sense of the experience;

4. Reviewing the transcript to identify the essence (In this study, an independent coder assisted with this process);
5. Developing formalised descriptions of the phenomenon (Guidelines were drafted based on the formalised descriptions);
6. Returning to participants to validate descriptions;
7. Reviewing the existing literature; and
8. Distributing the findings to the nursing community.

2.2.9 Special strategies in phenomenological research

The researcher approached the phenomenon to be explored with no preconceived notions. That ensured the phenomenon under investigation truly appeared in the way it was experienced (Omery, 1983, p. 50). Trust is a core component to phenomenological research, since the research findings need to reflect the reality of the experience (O'Gorman *et al*., 2013, p. 14). The researcher built rapport with the participants and was able to understand both the cognitive and subjective perspectives of the participants.

2.2.9.1 Intuiting

This step required that the researcher became totally immersed in the phenomenon under investigation; the topic became familiar to the researcher (Streubert & Carpenter, 2011, p. 81). The concept of the researcher as an instrument was essential and it is through intuiting that this principle was realised. (*The researcher initially worked within the clinical research industry in a permanent position at a clinical research organisation as a clinical monitor or clinical research associate during the course of this project, and subsequently during the data analysis phase took on a position as a clinical research nurse on a phase one clinical research study. This meant that the researcher had daily exposure to the environments that the participants were exposed to*).

2.2.9.2 Bracketing

This is the step when the phenomenological, qualitative researcher disregards any previous knowledge of the study topic (O'Gorman *et al*., 2013, p. 14). In this study, bracketing should be emphasised, since the researcher had been a clinical monitor for more than two years and had direct interactions with clinical research nurses. With this background, the researcher was

mindful of an inherent bias. Bracketing ensures that the interviewer does not allow such biases to cloud the interpretation of the data (O'Gorman *et al*., 2013 p. 14).

The researcher focused on a phenomenological approach that supported a critical self-awareness of the presence of subjectivity, vested interest, predilections, and assumptions. It enabled the researcher to go beyond her natural attitude by bracketing her presuppositions (Finlay, 2009). The researcher adopted that phenomenological attitude during the course of this study. The interviews were transcribed and non-verbal information was noted and added to the transcription (Mero-Jaffe, 2011; O'Gorman *et al*., 2013).

2.3 POPULATION AND SAMPLING

2.3.1 Population

The accessible population for this study was clinical research nurses in the southern suburbs of Cape Town in the Western Cape. The intent of phenomenological studies is to describe the participants' experiences rather than to generalise from their experiences to those of the whole population (Porter, 1999, p. 796). Porter (1999) describes the importance of determining the size of an eligible, accessible population. However, the researcher took a different sampling approach.

2.3.2 Sampling

The aim of this qualitative study was an in-depth investigation into the phenomenon of the clinical research nurse and how she experienced her self-leadership role (Bless *et al*., 2013, p. 175).

Probability sampling methods are too rigid and do not allow the investigation of phenomena about which little is known (Bless *et al*., 2013, p. 175). However, non-probability sampling enabled the researcher to select participants on the basis of who would be most informative (Baker, Brick, Battaglia, Couper, Dever, Gile & Tourangeau, 2013, p. 3).

Participants were chosen purposively based on inclusion and exclusion criteria (Bless *et al*., 2013, Gill, 2014). Professional nurses where selected, based on their knowledge about the existing nursing practice of clinical research nurses working in general nursing units in the southern suburbs of Cape Town. A particular purposive sampling technique is snowballing (Streubert & Carpenter, 2011, p. 29). This technique uses one informant to find another. For

the purposes of this study, the sample was deemed to be adequate when it allowed for all possibilities or aspects of the research area to be identified and no more participants were included in the sample only after no new details had been forthcoming (Bless *et al*., 2013, p. 164). This is known as sampling to redundancy and in phenomenological research it can vary between three to ten participants, with the overarching aim of sampling until redundancy occurs (Bless, 2013; Creswell, 2014).

Inclusion criteria:

- Professional nurse working in the southern suburbs of Cape Town;
- Working in the clinical research field for a period of more than one year;
- Either male or female; and
- Involvement in clinical trials in a general unit at public and private hospitals.

Exclusion criteria:

- Professional nurse working in the southern suburbs of Cape Town for less than one year.

2.4 DATA COLLECTION

2.4.1 Selection of interviewees and recruitment of participants

Interviewees were initially selected based on their location, as well as the current relationship that they had with the researcher. Afterwards, snowballing was used to elicit more participants. The researcher informed those potential participants about the proposed study via a telephone call and / or an email. Individuals who were interested in participating were asked to email or call the researcher. The ones who agreed to participate in the study then met with the researcher at a convenient location for the purposes of an interview.

2.4.2 Interviewing

Qualitative research adequately attempts to understand the ideas and emotions of individual participants (Polgar & Thomas, 2008, p. 86). A defining characteristic of qualitative research is the quest for rich, detailed, and in-depth data. The researcher sought to achieve this characteristic in this study by using well identified preparation strategies (Irvine, 2011, p. 211). Extensive interviewing is an important feature of phenomenology, while extensive and

accurate field notes form part of a well conducted qualitative investigation (O'Gorman *et al*., 2013, p. 14).

In a research context, an interview is best described as a dialogue or conversation between interviewers and research participants with the purpose of eliciting information from the participants to fulfil the researcher's particular needs for data (Polgar & Thomas, 2008, p. 107). It involves direct personal contact with the participant (Bless *et al*., 2013, p. 193). Open-ended interviewing allows researchers to ask leading and clarifying questions (Streubert & Carpenter, 2011, p. 90). Irvine, Drew and Sainsbury, (2013, p. 90) purport the importance of face-to-face interviewing that allows for visual signals that are important to the researcher. It encourages interviewees to elaborate or clarify what they have said, and they further suggest that this could solicit more 'thoughtful' responses.

The use of unstructured interviews in phenomenological studies in health care and social science research is known and is used when a researcher seeks to identify a specific phenomenon within a population whilst creating room for the essence of that phenomenon to be vividly described by the participants (Zhou, 2010). The research question was: *Tell me about your experiences in leading (directing yourself) as an independent clinical research nurse visiting nursing units?*

The face-to-face unstructured interviews permitted the observation of the non-verbal reactions of the participants and a closer rapport around their lived experiences (Polgar & Thomas, 2008, p. 108). The unstructured interview was helpful in this study, since it allowed for concepts, as well as problems to be clarified (Bless *et al*., 2013, p. 197). It did not impose a predetermined structure; therefore, the researcher could explore what were important to the participants (Bless *et al*., 2013, p. 216).

Field notes were taken during the interviews to obtain information not captured in the interview transcript (Creswell, 2014, p. 185). The researcher asked follow-up questions that compelled the participants to either reorder, or rephrase their statements. In order for follow-up to take place during an interview, an interviewer needs to listen attentively and free form note taking would assist with asking pertinent followed-up questions (Bless *et al*., 2013, p. 215). The participants' own words were used, since it showed respect and it served to retain the interviewee's meaning frames while not allowing the biases of the researcher to enter the interview process.

The role of the interviewee was to participate freely and without restraint. Since the interviewer created a comfortable and relaxed environment for open dialogue between the interviewee and interviewer, the interviewees used this opportunity to qualify their answers; most importantly, the interviewees gave an in-depth account of their lived experiences as clinical research nurses.

2.4.3 Role of the interviewer

The researcher assumed specific responsibilities in transforming the information from the interview. Since the researcher was the interviewer, she was responsible for creating an opportunity for lived experiences to be shared through verbal interaction (Streubert & Carpenter, 2011, p. 88). The interviewer used an open-ended question rather than closed questions with the view of creating an environment in which the interviewees felt comfortable to express their lived experiences (Bless *et al*., 2013, p. 214). The researcher used clarification, active listening, and empathy strategies to guide and encourage participants during the interview process (Burke, 2011, p. 167).

Inherent to understanding the personal meanings and subjective experiences of participants was the knowledge that the researcher had to become involved with the lives of the subjects being studied (Polgar & Thomas, 2008, p. 86). As the investigation progressed, the human instrument became more attentive to what was happening and the researcher started spotting the nuances in the participants' points of view more readily with the result that data collection became more accurate (Polgar & Thomas, 2008, p. 86). However, potential for bias accompanied this increased accuracy that required the use of specialised data analysis techniques to allow for these biases that might have been present during the data collection process.

2.5 DATA ANALYSIS

Data collection and data analysis in qualitative research begins at the same time (Streubert & Carpenter, 2011, p. 46, 91). Regardless of the methodological approach applied, the goal of data analysis is to illuminate the experiences of those who have lived them by sharing the richness of lived experiences and cultures (Streubert & Carpenter, 2011, p. 47).

Triangulation is a requirement to ensure the validity the findings of a study (O'Gorman *et al*., 2013, p. 14). In this study, the researcher used the unstructured interviews that started with

an open question in combination with interview notes and observation to achieve triangulation of data, which was analysed into one framework.

2.5.1 Defining the process

Tesch's model (1990) was adapted and used for data analysis; this was done within the ambit of a phenomenological methodology, since a phenomenological method remained malleable to incorporate emerging innovation in the field of research methods (Mayoh & Onwuegbuzie, 2013, p. 2).

The adapted steps that the researcher took to analyse the data and field notes were:

1. Transcripts were read and notes where made of ideas that came to mind;
2. One interview was selected to obtain a general view of of the content; substance and utility were not sought at this stage, since it would have obscures the data (Bruce, 2010, p. 4);
3. Similar topics were arranged into groups by forming columns labelled major topics, unique topics, and exceptions. The aim of this step enabled the researcher to gain an understanding of the underlying meaning of the data;
4. Topics were abbreviated into codes and more thorough observation was to check whether new categories or codes emerged;
5. The most descriptive words were chosen for the topics and those words were converted into categories with the aim of reducing the number of categories by grouping related topics;
6. The researcher abbreviated the categories and arranged those codes alphabetically;
7. Appropriate descriptive words were used to convert the coded topics into themes with the aim of analysing the data; and
8. The researcher and an independent coder held a consensus meeting to reach an agreement about the data analysis framework.

The capacity to use language is one of the defining features of human beings as a species (Bless *et al*., 2013, p. 340). The researcher acknowledged that words were the backbone of this study; her observations and thoughts added the finer detail to the experiences that the participants had expressed. As such, the initial analysis was based on the attention to those words. The ensuing processes crystallised the themes formed pertaining to the lived

experiences of clinical research nurses. Literature confirmed the findings from which conclusions could be drawn.

The aim of descriptive phenomenology is to set aside natural, everyday assumptions to return to the pre-reflective state with the aim of describing the phenomenon in its purest form as it occurred (Englander, 2012, p. 1). To this end, the researcher bracketed her own previous experiences.

2.6 QUALITATIVE RIGOR

2.6.1 Credibility

Lincoln and Guba (1985) described *credibility* as activities that increase the probability that reliable findings will be produced. It refers to confidence in the truth of the data (Polit & Beck 2012, p. 724). This study needed to be believable and the researcher took steps to demonstrate this quality. Firstly, she bracketed her own experiences. Field notes taken during interviews supported the data of the interview recordings and their subsequent transcripts. Additionally, the researcher described the interview process and techniques used during interviews, i.e. (probing) and the member checking process while an independent coder validated the data analysis process during a consensus meeting (Brink, *et al*., 2012, p. 173).

The goal of persistent observation was to identify characteristics, attributes, and traits that were most relevant to the phenomena under investigation and to focus on them extensively. The researcher separated relevant from irrelevant observations and aimed at providing depth to the research findings by her carefully selected data collection techniques (Onwuegbuzie & Leech, 2007, p. 239).

Reflexivity refers to the responsibility of a researcher to examine his or her influence on all aspects of this qualitative inquiry (Streubert & Carpenter, 2011, p. 34). The researcher regarded it as important not to allow her personal experiences as a clinical research nurse to influence her analysis of how other clinical research nurses experienced the implementation of their job descriptions.

The simplest verification of qualitative interpretations is to engage with the participants, in order to establish whether the researchers' interpretations make sense (Polgar & Thomas, 2008, p. 89). This act of consulting the participants after the data analysis process, was to

establish whether they identify with the truthfulness of the study findings is referred to as member checking (Streubert & Carpenter, 2011, p. 48). Due to the highly contested nature of member checking, the researcher did that partially (Bruce, 2010, p. 6) by sharing the analysis in the form of the themes and categories with the study participants to verify the accurate interpretation of the informants' views (Bruce, 2010, p. 6).

2.6.2 Transferability

This refers to the probability that the findings of a study have meaning in other similar situations (Streubert & Carpenter, 2011, p. 49). However, the expectation with regard to the *transferability* of the findings rests with the potential users of the findings and not with a researcher. A researcher's responsibility is to provide sufficient descriptive data in a research report to enable other interested parties to evaluate the applicability of the findings to other contexts (Lincoln & Guba, 1985, p. 316). In this study, the dense description of the research topic and the decision to use a phenomenological approach enhanced the transferability of the research findings.

2.6.3 Dependability

The *dependability* of a study can only be met once a researcher has established the credibility of the study findings (Streubert & Carpenter, 2011, p. 49). It refers to the stability of the data over time (Brink, *et al*., 2012, p. 173). Keeping accurate records of all the research steps that were followed contributed to dependability and made it possible to retrace all these steps.

2.6.4 Confirmability

Confirmability occurs when a researcher leaves a trail of research evidence that another individual could interrogate. It refers to objectivity or neutrality of the data obtained (Polit & Beck, 2012, p. 723). Confirmability ensures that the data reflects the participants' voice and not the biases of a researcher (Brink, *et al*., 2012, p. 173). Voice recordings of the interviews and the researcher's field notes of the interviews ensured confirmability. This enabled the researcher to scrutinise each interview while the ensuing themes were based on the voice recordings and transcripts of the interviews. The objective was to illustrate as clearly as possible the evidence and thought processes that led to the conclusions.

2.6.5 Authenticity

According to Polit and Beck (2012, p.720), *authenticity* refers to the extent to which researchers fairly and faithfully provide evidence about a range of different realities in the collection, analysis, and interpretation of data. The researcher ensured authenticity by including quotations from all the participants' interviews in the final report to describe their experiences. The researcher used the participants' own wording to describe a particular phenomenon. This approach enables the reader to understand the real experience of the phenomenon.

2.7 CONCLUSION

The chapter describes the research design, data collection, and analysis processes whilst taking into consideration the adequacy, trustworthiness, and ethical obligations of qualitative research.

CHAPTER 3
FINDINGS AND DISCUSSION

3.1 INTRODUCTION

A researcher uses the technique of data analysis to generate and describe essential findings, address research questions, and compile a research report that weathers the scrutiny of an expert review panel (Dierckx de Casterle, Gastmans, Bryon & Denier, 2012, p. 368). In this study, every participant was asked to describe their lived experiences as a clinical research nurse working in a general unit (first objective of the study).

The researcher conducted seven individual interviews with nurses who were between 35 and 60+ years old. The sample population consisted of individuals who were either white or coloured; however, the study sample predominantly consisted of white participants. The clinical experience of the participants ranged between 5 and 15 years. The settings where the participants worked ranged from onsite units to hospital wards and community health centres. The researcher used unstructured interviews to collect data until data saturation was achieved.

3.2 FINDINGS

Four main themes and twenty one categories emerged. The experiences of clinical research nurses seemed to evolve from an initial phase that was perceived as tedious and often daunting for a novice to a collaborative working phase when interpersonal relationships became critical. Specific traits and self-leadership behaviour were emphasised. Although the participants mentioned some challenges, their experiences in the main were positive.

While describing the findings, the researcher included verbatim transcripts without any corrections to grammatical errors in the supporting quotations. Each theme was divided into categories with relevant sub categories. These themes and their categories are individually discussed and supported by direct quotations from participants' responses. The researcher cites relevant literature to further support the findings.

Table 3.1: Themes and categories

Themes	Categories	
Initial tedious and daunting phase	1	Overcoming negative perceptions
	2	Selling the 'idea' project and benefits
	3	Building trusting relationships through interpersonal skills
	4	Collaborative partnerships
Working in pursuit of collaborative action	5	Develops over time
	6	Maintain quality and integrity in working projects
	7	Application of knowledge and skills
	8	Mostly positive and exciting new experiences
	9	Negative experiences
Personal traits of the clinical research nurse	10	Confidence
	11	Determination
	12	Professionalism
Self-leadership behaviour	13	Future focused orientation
	14	Goal setting
	15	Passion
	16	Prioritise
	17	Self-motivation
	18	Planning and organisation
	19	Leading through teaching
	20	Patient advocate
	21	Learning through experience

3.2.1 Initial tedious and daunting phase

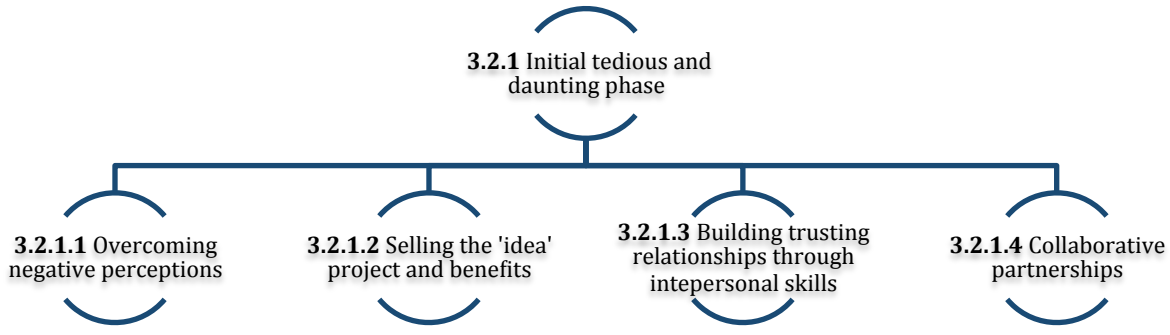

Figure 3.1: Theme 1: Initial tedious and daunting phase

The participants experienced an initial tedious and daunting phase while leading themselves in their practice.

Tedious can be defined as something that can be either time consuming or tiresome (Random House Kernermen Webster's College Dictionary, 2010). Tedious circumstances could be caused by lack of available support, missed opportunities for informal interactions with co-workers, and feelings of not being part of a group (Marshall, Michaels & Mulki, 2007, p. 196). One participant stated her challenge to maintain self-control during a period of time of repetition in her daily tasks:

> "*I found that as you go along, you know, if some, if you have to be very, very in control with your quality because what happens* [sic] *you yourself, you can do the same thing over and over again. It's very easy to get lax, you know, when you implement quality control guidelines…*" (P01)

A daunting task is regarded as an activity that causes fear, discouragement, or intimidation (Random House Kernermen Webster's College Dictionary, 2010). A participant described her fearfulness and need for a safe learning environment where her actions were protected, meaning that the responsibility should not ultimately rest with her only but collectively with the multidisciplinary team that she is a member of:

> *"I mean, the experience for me was, it was very daunting in the beginning but it wasn't so much so because I had a lot of it. It was an umbrella under which I was, I wasn't thrown in and expected to like perform this miracle. So, I was guided and protected."* (P01)

Participants initially found the tasks that they had to accomplish daunting in the context of their role as clinical research nurses. However, in a supportive environment they were able to cope. The uncertainty while conducting tasks indicated the need for support.

Research about the NHS of the UK reveals that among all health professionals, close to a fifth (18%) are of the opinion that they do not have the necessary skills to get involved in research. Some even report a lack of confidence in talking about research with their patients, with almost a third of nurses (31%) and GPs (34%) not very or not at all confident (Association of Medical Research Charities, 2013). The same research report reveals that professionals who enter the clinical research environment are uncertain and in need of support during the initial phase of their practice. Whilst many resources exist for clinicians about medical research and how to be involved, a fifth of health care professionals (20%) do

not use any of the tailored information resources that are available (Association of Medical Research Charities, 2013).

Participants felt discouraged and isolated as professional nurses starting out in clinical research**:**

> "*There was nowhere except to your CRA, your monitor, where you could go for help if you were stuck. You could perhaps phone another co-ordinator in another practice that you might happen to know but very often you don't know who is working on that study in other practices, especially when you're new to the job.*" (P04)

> "*Oh, I just had to learn myself.*" (P05)

It could be interpreted that these participants experienced their workplace isolation as tiresome. Perceptions of isolation have also been described in virtual teams, and the clinical research nurses could be viewed almost similar to a member of a virtual team. Hoch and Kozwolski (2014) identify challenges experienced by virtual teams (p. 390). During the initial daunting phase of her practice, the clinical research nurse may experience low levels of team cohesion, work satisfaction, trust, cooperative behaviour, social control, and commitment to team goals; all these factors could negatively impact team performance.

3.2.1.1 Overcoming negative perceptions

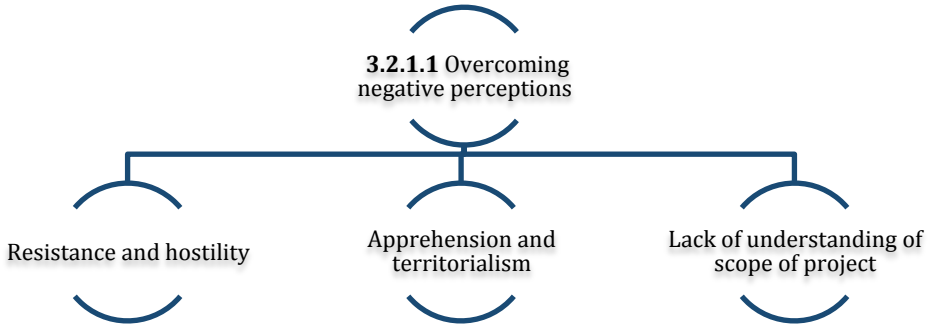

Figure 3.2: Category 1: Overcoming negative perceptions

Overcoming is defined as the ability to succeed in dealing with or controlling a problem (Macmillan Dictionary, 2014). Negative attitudes have been linked to feelings of powerlessness and a lack of choice (Hawkins, 1994, p. 26). This study found that for clinical research nurses who initially visited a general unit the possibility of a dysfunctional dynamic

existed due to the perceptions of nurses working in wards. A participant indicated that nursing staff initially did not have a positive opinion about the presence of "the outsider" whose presence they might not have been consulted about:

> "*If I am allocated in this area, I want my clients out by that time because I have other things to do and now you come into my area and want something from me. It puts them in a position where they think, these people are adding to my workload…*" (P01)

At the workplace, people seek to find their place in formal and informal work groups; individuals' perceptions of workload could affect the formation of these work groups (Mohamed, Newton & McKenna, 2014, p. 125). Feelings of powerlessness affect the formation of pleasant working relationships with co-workers in an environment where a perceived increase in workload becomes burdensome.

A previously quoted participant shared an opinion about how to deal with a problem:

> "*...you have to make sure that they understand that you are not adding to their workload and that is the main thing. If they think that you are going to add to their workload, that is going to give you like a lot of grief at the end of the day.*" (P01)

This alludes to an assertiveness strategy that could possibly be used by the clinical research nurse to achieve a pleasant working relationship. Assertive discretional transparency is defined as a mechanism of accountability, which the clinical research nurse can use to elucidate the needs and procedures of the research project whilst convincing the nursing staff that their cooperation would not add to their workload (Roberts, 2009, p. 958).

- **Resistance and hostility**

Emotions such as hostility drive workplace interactions (Hartel, Gough & Hartel, 2008, p. 22). These emotions are the result of an assessment of situations and are the product of individual emotional characteristics interacting with environmental characteristics. Clinical research nurses have the resilience they need to lead themselves while coping with disappointments and stress, mitigating and removing obstacles, recovering from or adjusting to change or misfortune, and dealing with the normal stresses and challenges of life (The

Psychology Foundation of Canada & Desjardins Financial Security, 2014, p. 2). Some of the clinical research nurses interviewed had no previous relationships with the nursing staff before they started visiting the nursing units (networking/ historical relationships) and experiencing resistance and hostility. A participant indicated her own initiative in building a trusting relationship with nursing colleagues to avoid hostility:

> "*It's almost like they can block your way. You can tell them ten times a day, you know, please and they would still not do it. You'll have to go there yourself. It's almost like with the children; it's like there's a trust thing there.*" (P01)

Another participant indicated that certain relationship skills influenced staff members to assist with the research process:

> "*We have built up a relationship with the sisters, the professional nurses that work in the units but we don't often find that they are willing to help us...*" (P07)

The findings indicated nurse-to-nurse hostility that presented an emotional challenge. Hostility fuels poor performance; affects satisfaction / retention in a unit; and creates concerns about the health, safety, and satisfaction of patients (Hartel, Gough & Hartel, 2008; Jones & Argentino, 2010). The self-leadership role of a clinical research nurse requires the ability to influence other people with the aim of removing resistance and hostility in order for effective people interaction to take place. Brewer and Strahorn (2012, p. 286) describe trust as a fundamental requirement to facilitate people interaction. Building trusting relationships are important, since they facilitate the completion of tasks. The lack of such relationships, however, creates a hostile and difficult environment to work in and affects whether a task would be completed timely or not.

Observationally, the researcher reflected on an inherent resilience of these nurses to withstand uncomfortable circumstances in order to achieve their goals.

- **Apprehension and territorialism**

Territorial change is often a painful process (Shaw, 1997, p. 378). A participant shared her initial anxiety about interacting with other nurses:

> "*...I find them territorial and slightly hostile initially...*" (P02)

"*...they become territorial in their area of expertise, that's really how they can make you feel unwelcome.*" (P02)

Clinical research nurses are sometimes viewed as "outsiders" . A participant described her own apprehension about the level of care that should be provided to her clients. Her negative outlook on students offered the researcher insight into the possible reasons for the apprehension often experienced by staff members in a similar situation when clinical research nurses enter their units:

"*I don't like having students looking after my patients. It's usually the normal* [sic] *staff and they have to do quarter-hourly temperature, pulse, blood pressure, respiration. But they're fine; they know what the study patients need.*" (P04)

This clinical research nurse described the importance of having experienced staff members to interact with her patients. That experience is analogous to the way in which experienced nursing staff view new graduates. Ballem and Macintosh (2014, p. 382) report that experienced nurses perceive new nursing graduates as disorganised, as well as without nursing skills and confidence.

- **Lack of understanding of scope of project**

A project is a temporary endeavour embarked upon to create a unique product, service, or result (Project Management Institute, 2013, p. 1). A project, therefore, has a definite beginning and end. The end is reached when the objectives of a project have been achieved, when the project is terminated because its objectives would not or could not be met, or when the need for the project no longer exists (Project Management Institute, 2013, p. 1).

Translation research as a discipline straddles the divide between clinical practice and basic science; clinical research falls within the ambit of translation research (Fang & Casadevall, 2010, p. 563). In that sense, clinical research attempts to merge two very distinct issues. The resultant clinical research study is wider and broader than the everyday clinical environment; individuals who are unfamiliar with this area of medical research struggle to grasp exactly what the practice, as well as its participants and practitioners are about. A participant shared the misperceptions of nursing staff about clinical research participants and staff:

"*They have no understanding of the nature of clinical trials and what's expected and so I think what's happened is, they seem to think it is a sub-group of patients that* [sic] *are being treated in a much more different vein and a little bit more elitist than the ordinary patient. So, they think that you come with that badge as well; that you're being paid an exorbitant fee because you're a contractor; that you bring with it these elitist patients and they don't quite understand it's just a different form of medical care.*" (P02)

Literature describes the difficulties of clinical research programmes as logistic constraints, socio-economic vulnerability of the study populations, weakness of a regulatory framework and an ethical review system, as well as the misperceptions of staff (Tinto, Noor, Wanga, Valea, Mbaye, D'Alessandro & Ravinetto, 2013, p. 612). The clinical nurse should thus share the vision of a project with nursing staff.

3.2.1.2 Selling the 'idea' project and benefits

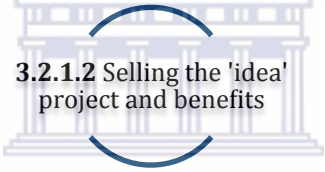

Figure 3.3: Category 2: Selling the 'idea' project and benefits

Selling is to find out why and under what circumstances the potential client would buy from you (Mattson, 2009). Nursing practice usually refers to "patient" based care but more and more service providers in the health sector refer to "client" based care. Nurses with a customer-orientated perception are in high demand (Chang & Chang, 2010, p. 629). This shift in thinking has proved useful to the clinical research nurse who is responsible for getting "buy in" from various stakeholders. A participant mentioned the depth of understanding and skills needed to achieve "buy in" in the vision, as well as the benefits of buy-in once it is achieved:

"*So, it's almost like you have* [sic] *to sell your product (vision), not just to the client but you have to sell it to the staff because always I think as nurses we don't want to be burdened with extra work. So if, you can ensure the staff in the facility that my presence here, me being here is not going to add to your workload. I am actually here to just relieve you* [from] *some of your workload, then you find a better relationship with them…*" (P01)

"*You need to make them understand that this is for the benefit of everybody at the end of the day. If I collect this data, this is the outcome that we are going to reach and this is how it's going* [to] *benefit the clientele, this is how it's going to benefit the staff.*" (P01)

Bleser, Miller-Day, Bricker, Cronholm and Gabbay (2014) identify some useful strategies for the clinical research nurse to achieve buy-in that could be beneficial when entering a new unit: (i) Ensure clear and concise communication and support from accessible practice leadership; (ii) educate, not just what and how, but why (vision); (iii) provide concrete information and guidance about known or learned techniques; (iv) provide constant feedback; (v) use external and internal data to benchmark, reinforce benefits, and emphasise successes; (vi) gain respect from other staff members who value clinical research; and (vii) concentrate advocacy efforts on sceptical or hesitant members ands dispel misconceptions (p. 40).

3.2.1.3 Building trusting relationships through interpersonal skills

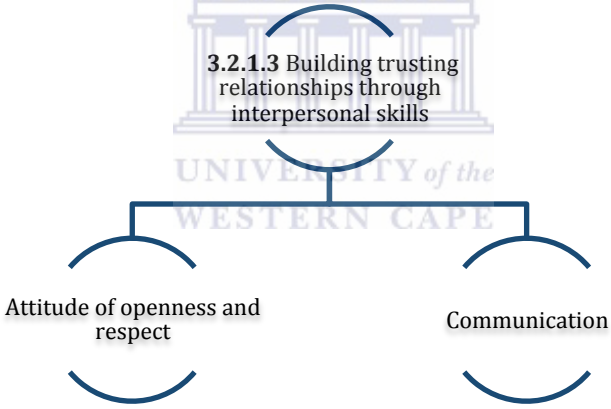

Figure 3.4: Category 3: Building trusting relationships through interpersonal skills

Trust is a critical element of leading oneself whilst building constructive human relationships (Moye & Henkin, 2006, p. 101). Relationships define and enhance the human existence and determine either success or failure at various levels in society. This is also true for nursing practice in the clinical research environment. A transparent, humble attitude enabled a participant to understand how to build and sustain a trusting relationship in an environment where she was viewed as an "outsider" (Section 3.2.1.1):

"*...you know who to ask for what, you got a relationship with them. They… I suppose it's a trust thing.*" (P03)

"*There is, I believe that everybody can make a mistake and as long as you acknowledge that you've made a mistake and you realise that you have and, therefore, you can do it right the next time, then that maintains the trust relationship.*" (P03)

Trust is an important ingredient of organisational change. Once staff members and employers trust the intentions of a clinical research nurse, they are willing to assist her and allow room for her to continue her independent practice (Lucas & Kline, 2008).

- **Attitude of openness and respect**

Openness is associated with candour, transparency, freedom, flexibility, expansiveness, and engagement. These qualities have emerged as distinct imperatives for managers who wish to organise themselves (Tapscott & Williams, 2006, pp. 20-21). Different strategies are used at the workplace to achieve the goals of a clinical research project. Two participants shared the importance of openness when dealing with staff members in a unit:

"*I always think you have to be open, you have to be transparent, you have to be polite, which is a given in any work environment…*" (P02)

"...so, we do get a bit of cooperation so they don't… are not always willing to help, but like I said, we've built a bit of a relationship so that they know us; they know what we're doing." (P07)

Respecting people means valuing their essential nature, which is an individual's ability to learn, grow, and reach self-actualisation (Dreher, 2002, p. 209). Openness establishes a trusting work relationship in which the clinical research nurse is able to practise self-respect and respect for other people while demonstrating humility during interaction with other nurses. A participant emphasised the use of humility as a resource to raise staff's awareness that they are respected:

"*…but I don't want to do it in a way that's going to offend you or your clients and even though I have my protocol, I have my job to do. I have to do it in a manner that is going to be respectful to you, towards the staff that's there…*" (P01)

The clinical research nurse leads herself and believes in the importance of the courteous treatment of people that invariably educes reciprocal conduct from them (Johnstone, 2012, p.

31). Clinical research nurses appear to be in the upper end of what personality research describes as the honesty-humility factor, which is associated with adjectives, such as sincerity and trustworthiness. Individuals at the higher end of the honesty-humility continuum are inclined to avoid exploiting other people (Ashton & Lee, 2008). Such traits equip and enable a clinical research nurse to successfully go about her daily tasks.

- **Communication**

Communication is regarded as a complex and dynamic system that assists people to interact with one another. Owing to different sensory networks, the nature of communication changes continually and influences both verbal and nonverbal messages (Buzatu & Pipas, 2014, p. 683). Two participants shared how valuable assertive communication is to self-leadership in their practice:

> "*…it's a matter of communicating and saying that's not working for me but is it working for you and not to be afraid…*" (P02)

> "*My interaction would be, firstly I would go to the head nurse of the ward and introduce myself and tell her what my purpose was. I might be coming to do an assessment on a patient for a research project, that would be the reason*." (P04)

The use of assertive communication allows the clinical research nurse to express her opinions and feelings clearly; strongly advocating for her rights and needs without violating the rights of other people (Buzatu & Pipas, 2014, p. 684). Assertive communication is an acquired skill and a characteristic of self-leadership (Section 3.2.1.1).

3.2.1.4 Collaborative partnerships

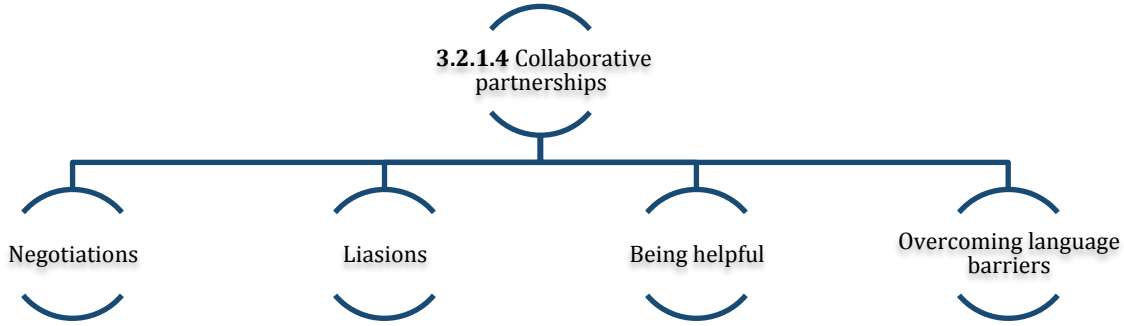

Figure 3.5: Category 4: Collaborative partnerships

Collaboration is the process when stakeholders create a social system for processing information that leads to discussions and actions (Lin & Beyerlein, 2006, p. 54).

A participant explained that a closer relationship needs to be formed with staff members as a collaborative initiative:

> "*…we interact with them on a much more, much more closer* [sic] *level. So, now you find that they recognise you, refer the people back to you so that's the kind of thing that you find…*" (P01)

Studies show that nurses might have a more positive attitude than doctors to collaboration, teamwork, and team training. In the clinical research environment, collaborative partnerships are a form of strategic thinking that enables clinical research nurses to facilitate the completion of tasks (Hansson, Arvemo, Marklund, Gedda & Mattsson, 2010, p. 84). A collaborative partnership requires a clinical research nurse to engage in relationship-centred practice that is mutually respectful and trusting. The promotion of a collaborative relationship centred partnership requires "buy-in" from nursing staff. Nursing staff members need to invest time in order to understand the motivation of the clinical research nurse and collectively they need to define what they hope to accomplish. This approach allows the clinical research nurse to address challenges in a manner that provides opportunities for all partners to contribute to finding solutions (Dewar & Cook, 2014; Hansson, Arvemo, Marklund, Gedda & Mattsson, 2010).

- **Negotiations**

To negotiate is the ability to deal or bargain with another person or persons and to confer with another with the aim of arriving at a settlement of some matter (Gourlay, 2007, p. 17).

A participant shared how discovering and utilising the expectations of the staff members enabled her to reach a workable solution for care that needed to be delivered to the patient:

> "*…what we had to do was if the clients come in and I take blood, then I would negotiate with the staff what if you refer the patient to me? I will take also take* [sic] *the blood that you require for me to take, like they would do the blood pressure and then I would say just send them to me for the blood sample so that number one, we do two things for you. You don't send the patient back and forth to be pricked on this this* [sic] *side and then go again to have blood taken. Also, you decease* [sic] *your workload for the staff and that and the thing is, they appreciate that because they have less to do...*" (P01)

Clinical research nurses take cognisance of the fact that they are negotiating a relationship and not a transaction; by doing this, they are able to navigate the complexities of being an "outsider" in a unit (Craver, 2007, p. 102).

- **Liaisons**

Levy, Klinger, Galinsky, DeKrey and Lester (2014, p. 14) describe the independent role of the clinical research nurse in clinical trials as an individual who works in close relationship with principal investigators, nurses, and the data coordinating centre when a need exists to develop a protocol.

A participant mentioned the value of developing liaisons at the units she visited:

> "*…you liaise with people and then you like you connect with people and that becomes the basis from where you work. That's how I find it, or how I go about it.*" (P03)

> "*I've identified an enrolled nursing auxiliary who usually looks after making sure that the observations are done properly and I've given her a little chat about interpretation of blood pressure, pulse, and temperature and the correlation*

between the three so that she doesn't just write it down like a robot; that she knows when to call for help..." (P03)

The liaison role of a clinical research nurse is not independent on her practice in units where she has a presence. Her self-leadership skills could enable her to develop associations that expand her intergroup role to communicate with nurses at institutions and in community settings that she visits.

Creative collaborative possibilities become a reality for the clinical research nurse and expedite the collection of quality data in a research project. These possibilities depend on skills; such as building and maintaining a relationship with one or two individuals in a unit, encouraging questions and conversation about nursing practice, as well as advising on issues, policies, and procedures (O'Neill, Lewis & Carswell, 2011, p. 596).

- **Being helpful**

A helpful person either provides assistance or serves a useful function (AudioEnglish, 2005). Being helpful enabled a participant to practise self-leadership with the overarching purpose being the effective performance of her task:

"*You have to like, somewhere you have to convince them that you actually are going to help. It takes a while, but most of the time I find it easy to get data*." (P01)

There is a synergistic relationship between high task performance and helpfulness. Helpful behaviour emphasises cooperation and supports harmony and positive working relationships (Kiker, Kiker & Perry, 2013)

- **Overcoming language barriers**

  A participant discussed the challenges of communicating with patients when they spoke different mother tongue languages. She raised concerns about the ability to embark upon a comprehensive assessment that formed the basis for the provision of quality care:

"*And it was much more difficult for us when we were working in… because we had a language barrier also…*" (P04)

Language barriers could be removed with the use of an interpreter. An interpreter is able to inform the assessment process and care provided to research participants (McCarthy, Cassidy, Graham & Tuohy, 2013). However, acquiring such services has its own challenges and rewards in the context of clinical research nursing in the southern suburbs of Cape Town.

3.2.2 Working in pursuit of collaborative action

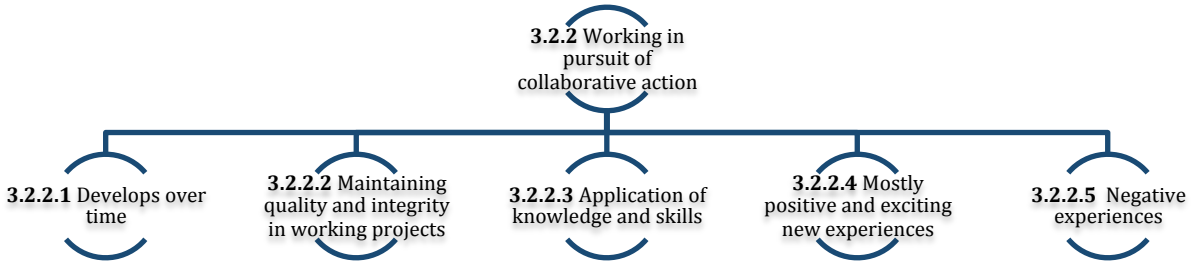

Figure 3.6: Theme 2: Working in pursuit of collaborative action

Collaboration is defined as the process that enables shareholders to create a social system for processing information that evokes discussions and actions (Lin & Beyerlein, 2006, p. 54). A participant described how sharing her knowledge while engaging with an individual enabled her to receive cooperation from staff members:

> "*…so it's always good to… what I've done, I've identified an enrolled nursing auxiliary who usually looks after making sure that the observations are done properly and I've given her a little chat about interpretation of blood pressure, pulse, and temperature and the correlation between the three so that she doesn't just write it down like a robot; that she knows when to call for help*." (P03)

Self-leadership enables clinical research nurses to focus on what they are capable of doing and to be the best that they could possibly be. Such an attitude attitude enables them to not shy away from helping and teaching other people (Bryant & Kazan, 2013). Self-leadership assists one to understand how a topic should be presented to other people in a more comprehensible way and how a task could be delegated whilst retaining accountability for the outcome (Bryant & Kazan, 2013).

3.2.2.1 Develops over time

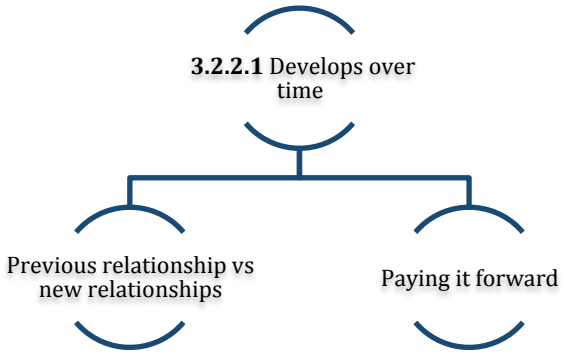

Figure 3.7: Category 5: Develops over time

In order to build relationships that progress over time, the clinical research nurse has to acquire leadership skills. Apart from self-leadership, the shared style is a dynamic, interactive, and influential process among individuals who share the objective of leading one another to the achievement of collective goals (Pearce & Wassenaar, 2014, p. 9).

A participant reflected on the irresponsible behaviour of members of staff in a nursing unit:

> "*It's almost like they can block your way. You can tell them ten times a day, you know, please and they would still not do it. You'll have to go there yourself. It's almost like with the children. It's like there's a trust thing there.*" (P01)

By utilising the concept of shared leadership, the clinical research nurse could influence nursing staff member to behave less antagonistically and irresponsibly by behaving more cooperatively and helpfully. Shared leadership should be considered within the context tasks in the nursing unit that require a certain degree of interdependence (Pearce & Wassenaar, 2014, p. 10).

- **Previous relationships versus new relationships**

In the context of this study, previous relationships versus new relationships could be defined as a strategic alliance that recognises the state of interdependence of alliance partners (Das & Kumar, 2011).

A participant explained how the creation of strategic alliances in a clinical setting facilitated continual recruitment of participants:

"*...so, initially we had to like run after them to go and get clients to remind them but now that we've been there and they've seen our work and we interact with them on a much more, much more closer level. So, now you find that they recognise you, refer the people back to you. So, that's the kind of thing that you find.*" (P05)

The alliance formation process is portrayed as a mixture of interpersonal and inter-organisational activities that require individuals to become more responsible for creating alliances (Olk & Elvira, 2001).

- **Paying it forward**

A participant reflected on the ease with which generalised reciprocity could be practised in the everyday activities of a clinical research nurse (Rankin & Taborsky, 2009, p. 1913).

"*It's not just, they're going to come here, take the data and run away. This is actually a beneficial thing for you that you can pay forward, so you find that all sorts of people just come in there and what we try to do is have like an open door policy. So, if you come and we have a little space for you, staff can come have their blood pressure taken and things like that...*" (P06)

Van Doorn and Taborsky (2011, p. 2) state that "generalised reciprocity requires minimal cognitive abilities and very little information retention and retrieval." Whilst the mentioning of an "open door policy which allows for staff's blood pressure to be taken if there is space" is not a direct act of kindness, the clinical research nurse serves as an example of the theory proposed by Gray, Ward and Norton (2014, p. 253). This theory proposes that by treating other people as equals, a chain of positive behaviour could be created. This chain could serve to assist the research nurse with leading herself during daily practice.

3.2.2.2 Maintaining quality and integrity in working projects

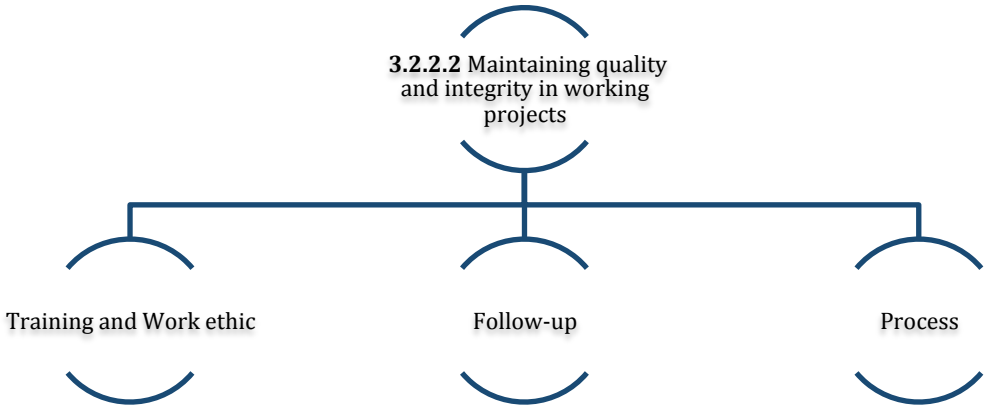

Figure 3.8: Category 6: Maintaining quality and integrity in working projects

The foremost quality of the ideal ethical nurse is moral integrity that represents the wholeness of character (Butts, 2002, pp. 72-73). Nurses with moral integrity act consistently with personal and professional values (Butts, 2002, p. 73). Participants reflected on how their moral integrity guided the "how" and the "why" of their practice:

> "*...the best of my ability is to ensure that whatever work is being done is of a high quality and to ensure that, you know, that I do what is required of me within the time period that I need to do this because you know how research is. You work within a timeframe. So, I have to ensure that I reach goals that was* [sic] *set by the protocol, by the people that* [sic] *pay for the study and things like that...*" (P01)

> "*I am a nurse first and a study co-ordinator second and so when I say I'm not going to marginalise I'm not going to marginalise the standard that I'm expecting from myself for any protocol and for any ward and for any medical personnel.*" (P02)

> The self-leadership ability of a clinical research nurse nurtures her inner capacity to practise professional nursing accountability. Accountability requires taking responsibility for one's nursing judgements, actions, and omissions with regard to life-long learning, maintaining competency, and upholding both quality patient outcomes and standards of the profession. In this sense, a clinical research nurse remains answerable to the ones who are influenced by her nursing practice (Krautscheid, 2014, p. 46)

- **Training**

Weaver, Dy and Rosen (2014, p. 360) define team training as a constellation of content (i.e. the specific knowledge, skills, and attitudes that support targeted teamwork competencies), tools (i.e. team task analysis, performance measures) and delivery methods (i.e. information, demonstration, and practice-based learning methods). These three elements represent an instructional strategy. Two participants shared the importance of regular study specific training:

> "*…in-service things we do to just refresh everybody how to do this. Do you still remember what you must do? So, we try to do it regularly, maybe every two months… continuously training.*" (P01)

> "*...But I prefer to have them in the day ward because the day ward nurses have been trained and they know exactly what's needed and they know how important it is because it has to be documented...*" (P03)

> "*I find that it's better not to interfere. I've given them the training, they know what they have to do, and I don't want to step on toes.*" (P03)

Different levels of research knowledge and experience among team members require that regular training on different levels is conducted (Phillips-Salimi, Donovan Stickler, Stegenga, Lee & Haase, 2011).

- **Work ethics**

Work ethic is a multi-dimensional concept founded on the beliefs and values of self-discipline, deferred gratification, acceptance of society as just, focus on work, self-reliance and independence, thrift, acceptance of authority, and striving for success (achievement orientation). By incorporating these beliefs and values, one leads a more enjoyable and financially rewarding life (Dunn, 2013, p. 3). A participant mentioned the need for work ethics:

> "*…you must be knowledgeable about your field, you must be pleasant, and you must have a good work ethic and those are the things that then will empower you to become part of the team…*" (P02)

Five traits are considered to be the foundation of a positive work ethic: responsibility, self-esteem, sociability, self-management, and integrity or honesty. The clinical research nurse could have an impact on a positive work ethic by developing and displaying these personal qualities and work values (Fox & Grams, 2007, p. 64).

- **Follow-up**

Clinical research follow-up is viewed as the act of renewing contact with study participants with the aim of assessing the objectives or outcomes identified in the study protocol. Follow-up could be done in various ways: a telephone call, electronic interactions (SMS / email), or a face-to-face visit by a member of the study team (home / unit).

Participants reported their site follow-up retention strategies by applying the principles of self-leadership:

> "*...about a week in advance and then if I'm in the hospital then I always just go pass* [sic] *the day ward and just check that the patients are on the list; 99% of the time they are and if they aren't then they'll always find them a bed somewhere.* " (P03)

> "*...explain to them when they have to come back to for* [sic] *their next appointments and then we will give them our phone numbers. So, they've got 24-hour access to us so that if they're worried about their little one or themselves, we do adult and child study, they can then contact us and just say my child's not well, what I do. We will then say take it to the day clinic or bring it into us for an unscheduled visit or, you know. Have you been to the doctor, what did the doctor give you? Was it antibiotics, or wasn't it? And so we will readily communicate with them on a very daily and* [in an] *intense manner so that you can then follow it up with telephone calls to find out how the child is doing and then just follow them at regular intervals and make sure they come back to their appointment at the required time because appointments have to be done at the specific time according to the protocol and within the window period so they can't, the patients can't say now they want to come at that time. You have to make sure that they can come, that there are window periods, four days or seven days so that… and we work with them in those time frames*." (P06)

When the research can be integrated into routine care, follow-up opportunities and information retention increase (Woolard, Carty, Wirtz, Longabaugh, Nirenberg, Minugh, Becker & Clifford, 2004, p. 861).

- **Process**

The clinical research process requires step-by-step planning of different activities in order to successfully implement and execute a project (The Global Health Network, 2014). The clinical research nurse is involved in various processes throughout the duration of a clinical research study. A participant detailed an example of accountability with regards to a product process:

> "*The drugs… you have to follow the system of the drug, it's delivered, you've got to acknowledge it, you've got to file it away in certain places, you've got to check it. So all there, that's a system of drug handling*." (P04)

A drug accountability process should be initiated for any study that uses study supplied drugs. Maintaining drug accountability includes careful and systematic study of drug storage, handling, dispensing, documentation, and administration (Friedman, 2007, p. 487) .

- **Recruitment of participants**

Recruitment in the clinical research environment is an interactional activity. Typically, it occurs after at least two meetings between each potential participant and clinical and / or research staff members to establish whether the participants are eligible according to the formal criteria in the protocol. When they are, the information and details of the study are provided after which a discussion about the decision to participate follows. The recruitment process concludes with the signing of a consent form (Donovan, Paramasivan, de Salis & Toerien, 2014). A participant described the challenges experienced when screening and recruiting participants for a study:

> "*They don't, they just don't seem to be doing trials. There are a lot of, you know, inclusion / exclusions are very stringent for X* [excluded to maintain anonymity] *We just seem to have a problem recruiting. I don't know if the doctors have lost the will to do research*." (P05)

"*Look, the screening procedures for these trials, particularly X* [excluded to maintain anonymity]*, we do mainly X* [excluded to maintain anonymity]*, are quite lengthy and involved and over a… quite a couple of weeks, there are a lot of blood tests. There are* [sic] *scoring*…" (P05)

Huynh, Su-Hsun Liu, Vedula, Li and Puhan (2014, p. 7) identify the cost-effective strategies for recruiting participants; namely monetary incentives, direct contact, and medical referral. Methodological studies need to report cost effectiveness strategies for recruitment, retention, and follow-up of trial participants. Such reporting supports investigators to design high-quality, cost-efficient health research studies that include clinical trials (Huynh, Su-Hsun Liu, Vedula, Li & Puhan, 2014, p. 7). Proactive assessment of site differences facilitates the development of a recruitment protocol with enough flexibility and customisation to make a successful recruitment process possible (Fairbanks, Shah, Wilde, McDonald, Brasch & McMahon, 2014, p. 4)

- **Information sessions with stakeholders**

A stakeholder is an "individual or group who is responsible for or affected by health and health care related decisions that can be informed by research evidence" (Concannon, Meissner, Grubaum, McElwee, Guise, Santa, Conway, Daudelin, Morrato & Leslie, 2012, p. 986). A participant emphasised the importance of sharing knowledge with stakeholders when visiting a unit:

"*…speciality because nurses did not have a great knowledge of rheumatology… I do all the lupus studies. So, I have on various occasions given them a quick talk on lupus and how to manage patients and the reason for each specific study and then I've also given separate talks to the staff on anaphylaxis because that* [is] *our biggest thing because we're infusing proteins and even after people have had twenty infusions they can have a reaction at infusion no. twenty-one. So, apart from that I give them written instructions according to the protocols and then also we have a very close relationship with the Arthritis Association and they bring out pamphlets so I regularly thank them. If they ask for them then they, if they want to know more, it's much easier to see it in a pamphlet*." (P03)

In her self-leadership role, the clinical research nurse contributes to the professional development of other members of staff. Professional socialisation with the clinical research

nurse and her clinical practice knowledge assists other people to develop as a result of their interactions with her (Weis & Schank, 2002, p. 272).

- **Assist with informed consent**

Informed consent can be envisioned as a spectrum ranging from routine paper work or a courtesy gesture to: (1) obtaining honest permission (simple consent), (2) obtaining informed permission (informed consent), (3) reaching shared patient-clinician decision making, and (4) enabling patients' self-decision making (Hammami, Al-Jawarneh, Hammami & Qadire, 2014, p. 1).

A participant commented about the participatory nature of informed consent in the clinical research environment. She described a collaborative process between the clinical research nurse and the patient:

> "*Look, what I do is I give a patient a consent. I give someone who's interested (in fact I must get that woman's folder), I'm just thinking something else. I give her, because they take so long. I say take it home, read it, think about it, then I phone them in about a week. Have they got any questions? Are they potentially interested? Yes they are, then I ask X to have a look at the folder and if she says they would work, then I would call the patient in and we would start the screening and then she would, she normally signs because if you look at consent, it's usually the PI* [Principal investigator] *and the patient that* [sic] *needs* [sic] *to sign the consent*." (P05)

Hammami, *et al*. (2014) describe the purpose of informed consent as giving patients the opportunity to be autonomous rather than forcing them to take part in treatment. This perspective is true in the lower and middle income countries where community members who are potential research participants need to make an informed and voluntary choice whether to participate or not. However, this choice must be as a result of autonomous decision making (Bristol & Hicks, 2014).

- **Collect data (anthropological measures, bloods, BP, etc.)**

Data collection is the process of gathering and measuring information about variables of interest in an established systematic fashion that enables one to answer stated research

questions, test hypotheses, and evaluate outcomes with the emphasis on ensuring accurate and honest collection (Northern Illinois University, 2014).

A participant pointed out the importance of influencing and overseeing field workers during data collection to ensure data quality:

> "*...So I have to ensure that everybody that's* [sic] *involved in having to collect the data, like the field workers that do the anthropometry; I have to ensure that they collect the correct data, that they store it correctly the way we want it to be stored so that we can have access to it at a later date*." (P01)

She further described the importance of maintaining data collection quality throughout the "life of the clinical trial":

> "*…when dealing with the field workers and data collection and the thing that I found that as you go along, you know, if some… if you have to be very, very in control with your quality*." . (P01)

Another participant described the increase in the volume of data as challenging:

> "*…your correspondence files are one or two instead of only half and there's just a lot more data that they want you to capture so they want you to keep, you know, better and more records*." (P06)

Philips-Salimi, Donovan Stickler, Stegenga, Lee and Haase, (2011, p. 10) identify a data collection integrity monitoring plan as a tool to assist with facilitating quality data collection. This plan includes: (a) generating regular reports of data quality for distribution to appropriate team members, (b) identifying and correcting problems by developing case studies for continual education, and (c) creating a final report of all quality assurance efforts, including protocol adherence and deviations, for use during the interpretation of findings (Philips-Salimi *et al*., 2011, p. 10).

In addition to these process features, they refer to standardised training of all study personnel; the use of database tracking of recruitment, accrual, and retention; and a two-level process for identification of adverse events that their team utilises (Philips-Salimi *et al*., 2011, p. 10).

- **Entering data into database**

Accurate data recording (entry) is equally important to avoid serious bias in the research process. Inconsistent data recording is due to incomplete data (missing) and incorrect data (errors) (Beretta, Aldrovandi, Grandi, Citerio & Stocchetti, 2007, p. 903).

A participant articulated how data capturing activities served as her introduction to clinical research:

> "*I started off doing data capturing for one of the doctors who was doing the study herself and that's how I got into it…*" (P03)

Another participant described her current data entry role:

> "*I do all the data, entering of data, arranging of whatever it is, ECG's* [electrocardiograms]*, MRI's* [magnetic resonance imaging]*, whatever they require*." (P05)

By engaging in data capturing, a clinical research nurse assists researchers and practitioners to understand the self-regulatory, goal-motivated orientation of her self-leadership role (Chan, 2014). The evolution of an internal willingness to acclimatise to a new environment whilst maintaining a strong sense of self and purpose enables a person to continue with task-related efforts (Henry, 2013).

- **Supervising fieldworkers**

Fieldworkers or first-line research staff members are those individuals who engage regularly, face-to-face, and over a period of time with participants and patients (Madiega, Jones, Prince & Geissler, 2013, p. 22). The researcher has conceptualised the supervision of field workers as the management of the role performance of the field worker in accordance with the description laid out for field workers in the delegation of duties log for a particular clinical trial. This supervision potentially may include aspects of problem solving, reviewing records, and observing their practice (Bosch-Capblanch, Liaqat & Garner, 2011, p. 5).

A participant described the quality control challenges faced when performing interdisciplinary supervision:

"*I must say that the clinical side of things was much easier to manage than the HR side of things when dealing with the field workers and data collection and the thing that I found that as you go along, you know, if some… if you have to be very, very in control with your quality because what happens is you yourself you can do the same thing over and over again. It's very easy to get lax, you know, when you implement quality control guidelines. Also, with the field workers trying to get them to, you know, do the questionnaire; administer the questionnaire in the same manner that you want it to be done. So, the challenge for me as we grew and as the project grew was actually to ensure that the quality of data that we collected was on par with the quality of data we collected initially*." (P05)

The clinical research nurse is a supervisor of clinical research field workers. Her supervisory role includes ensuring the collection of quality data through strategies, such as quality control guidelines. This supervisory role possibly includes the self-responsibility of the clinical research nurse to use her self-leadership skills for appropriate support of her field workers. Such support would strengthen ethical research practice and facilitate the long-term sustainability of research programmes (Madiega *et al*., 2013).

- **Coordinate research / project team**

For the purpose of this study, coordination of a research project or team is congruent with study management. Study management ensures that the clinical and research activities are in order, patient safety is assured, clinical needs are addressed, protocol integrity is maintained, and accurate data is collected (Hastings, Fisher & McCabe, 2012, p. 5). Participants explained the various responsibilities of their study coordination role:

"*I'm actually employed here as a study coordinator…*" (P05)

"*I do everything here, every single thing except the physical examination which the doctor does, you know, which the PI does but I do everything. I do all the consent documents, I liaise with the sponsors, I do all the data, entering of data, arranging of whatever it is, ECG's, MRI's, whatever they require.*" (P05)

"*…working, having to oversee your field workers because initially when you recruited the field workers we had a lot of training. So, we trained them how we want things to be done, the procedures, the protocols, follow the SOP*." (P01)

The role of a clinical research nurse is also sometimes included in the description of a study coordinator's role. When advertising for the position of a study coordinator, the University of Cape Town (2014) identifies several roles and responsibilities related to clinical research for potential study coordinators. The job profile includes leading research activities and generating regular and ad-hoc reports as required by investigators. Whilst job descriptions exist for study coordinators, there are neither local nor international guidelines that are standardised for clinical trial management (Farrell, Kenyon & Shakur, 2010, p. 6). Currently, the clinical research nurse has to rely on her professional nursing competences and self-leadership abilities to guide her during the performance of her job.

3.2.2.3 Application of knowledge and skills

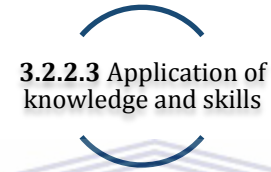

Figure 3.9: Category 7: Application of knowledge and skills

The South African Nursing Act (2005) describes the skills and knowledge needed to qualify as a registered nurse. Qualification means a planned combination of learning outcomes with a defined purpose that are intended to provide qualifying learners with applied competence for meeting the requirements for professional nurses which are registered as a National Qualifications Framework (NQF) at the South African Qualifications Authority (SAQA). The applicable NQF of the Health and Welfare Sector Education and Training Authority (HWSETA) meets the prescribed requirements for registration as a professional nurse (Government Gazette of South Africa, 2014, p. 4). Competence means the ability of a practitioner to integrate the professional attributes including – but not limited to – knowledge, skills, judgment, values, and principles required to perform the duties of a professional nurse in all situations and practice settings (Government Gazette of South Africa, 2014, p. 2).

A participant described how decision making as a competence assisted her with transitioning into her new role in clinical research:

> "*I think one can apply your knowledge quite a bit…*" (P07)

> "*You have to be very precise and you know there's no room for error. So, you know because the sicker the patient, the more I liked it. So, and I think there is no*

room for mistakes and I think that the type of personality of a critical care nurse is, I think, more or less the same as the clinical trials because, you know. If it's not right it's wrong. So, the transition wasn't difficult on that level." (P07)

Evans, Bell, Sweeney, Morgan and Kelly (2010, p. 340) also identify autonomous decision making as a competence of critical care nurses that enhances job satisfaction and affiliation to the multidisciplinary team.

3.2.2.4 Mostly positive and exciting new experiences

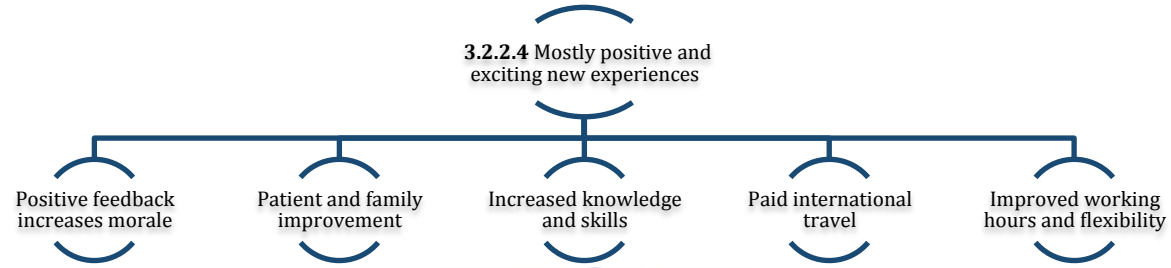

Figure 3.10: Category 8: Mostly positive and exciting new experiences

Positive emotions enhance problem-solving, improve certain types of information recall, increase efficiency in highly complex decision-making, and lead to more cooperative approaches during conflict resolution (Lutgen-Sandvik, Riforgiate & Fletcher, 2011, p. 3). There is evidence that positive experiences increase personal resources by expanding cognitive processes and improving physical and mental performance (Lutgen-Sandvik, Riforgiate & Fletcher, 2011, p. 3).

A participant reflected on the gains while working in clinical research:

> "*Like eczema patients; when they come covered in eczema and then you treat them on this medication and in the next hour and their skin is rosy and shiny and everything. It's just so exciting, it's not this dry, sore skin and the kids are scratching like mad and now they're sleeping and now they're smiling and happy and all that sort of thing*[s]. *It makes a huge difference*." (P06)

> "*You get to travel and work and they pay for it and you travel with these interesting people. So, it's actually very nice, very exciting.*" (P06)

It seems that clinical research nurses influence themselves to commit to work engagement. Engaged employees often experience positive emotions, including happiness, joy and enthusiasm (Rodriquez-Munoz, Sanz-vergel, & Demerouti, 2014, p. 279).

- **Positive feedback increases morale**

Feedback is conceptualised as the information provided by a clinical research stakeholder in relation to aspects of an individual's or team's understanding or performance (Hattie & Timperley, 2007, p. 81). A participant described the value of acknowledging good work:

> "*When we get positive feedback from drug companies or CROs* [Contract Research Organisation] *about the quality of the data, you know the timelines and everything that we're doing. So, it's nice to strive to do something good and you actually get acknowledgement because you have done a thing well*." (P07)

When the orientation of clinical research nurses are behaviour focused, it is likely that feedback would be an opportunity for learning, as well as for improving performance (Mulder & Ellinger, 2013, p. 19).

- **Patient and family improvement**

Patient- and family-centred care is grounded in collaboration. This collaboration occurs: (1) among patients, families, physicians, nurses, and other professional in clinical care; (2) for the planning, delivery, and evaluation of health care; and (3) in the education of health care professionals and in research. (Committee on Hospital Care and Institute for Patient and Family - Centered Care, 2012, p. 395). Participants described the joy experienced when observing patient improvement after a clinical trial treatment:

> "*In some ways it's nice to see people getting better, even though I might not think that they're getting better, they in themselves feel that they're getting better which is quite interesting*." (P03)

> "*...but when you see the patient improving on medication and seeing new medication come out on the market which is just so much better than the old medication, then the patients aren't having to land up in ICUs and all this sort of thing and their parents are saying, gee! Little Johnny has been so much better since he's been on this medication. You feel very motivated and you want to see*

the whole quality of the family, not only of the patient, but the whole family has improved, it really is, you know, great." (P06)

"*The patients, completely the patients and because I make it interesting for myself…*" (P07)

As professional nurses, clinical research nurses use natural rewards strategies to obtain their mission of caring for people in times of their greatest vulnerability and need, this allowed them to find meaning in their work (Lucian Leape Institute, 2013, p. 1).

- **Increased knowledge and skills**

Participants reflected on how clinical research associates or monitors helped develop their competency:

"*Each trial is different, one has to be versatile in what one does and, but I did find that our CRAs or our monitors, given the right one of course, were extremely helpful but they're obviously aren't there to train one. So, the X that one worked with as the principal investigators, they themselves were not trained in any formal way in research*." (P04)

"*So, I spent a lot of time on the phone to monitors. Look, I had to do the GCP* [Good Clinical Practice] *course, which is a prerequisite anyway, but I literally spent hours on the phone with monitors and that is how, basically I learnt really…*" (P05)

Policies and procedures can be read but learning through experience plays a critical role in determining when and how to apply, adopt, or abandon those policies and practices (Noe, Clarke, & Klein, 2014, p. 246). A clinical research nurse could use her self-influenced skills development to acquire tacit knowledge from a clinical monitor; it will stand her in good stead to perform research-related duties successfully amidst challenging circumstances.

- **Paid international travel**

Travelling professional workers are individuals who work while travelling; they apply an instrumental orientation toward their excursion and perceive tourist-like pursuits (Uriely,

2001, p. 2). A participant reflected her working activity gave her the opportunity to travel both locally and internationally:

> "*...one nice thing about it is with each study you go on investigator meetings and these things and the investigating teams can be local; Cape Town, Johannesburg, Durban, Drakensberg, or whatever. So, in South Africa… right through the rest of the world and so I've travelled a lot and I enjoy travelling. So, I've been to Buenos Aires, I've been to Budapest, I've been to Barcelona, Paris, Cologne, you know, all these places*." (P06)

> "*You get to travel and work and they pay for it and you travel with these interesting people...*" (P06)

- **Improved working hours and flexibility**

A clinical nurse researcher is usually seen as being a part-time independent and location-independent person; this role sometimes gets described as "partial blended working" (Van Yperen, Rietzschel & De Jonge, 2014, p. 2).

. Participants describe the flexibility of their job:

> "*...I have flexibility*." (P02)

> "*It's a very nice job, especially if you have a family and you don't want to work ward hours, it is a Monday to Friday job*." (P06)

> "*...because of the hours, we have worked night shifts but for clinical trial purposes an hour here or there, you have to come in to do blood tests and things like that but it suits my family to work in the hospital in this way*." (P07)

The consequences of work flexibility on work-life balance, psychological health, and work performance are becoming increasingly relevant and important. Through increased flexibility and a better work-home balance, blended working might have substantial positive consequences for workers' effectiveness and quality of work and life (Van Yperen, Rietzschel & De Jonge, 2014, p. 2).

3.2.2.5 Negative experiences

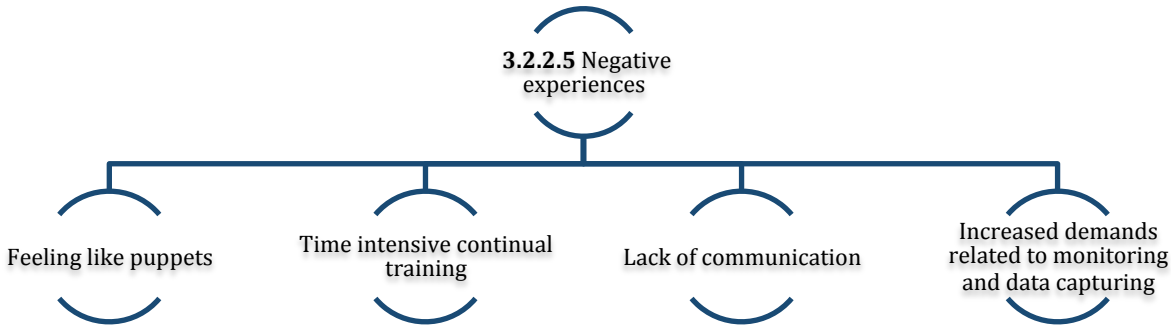

Figure 3.11: Category 9: Negative experiences

A negative experience usually has a bad influence on one's state of mind and it makes one more vulnerable (Bryant & Kazan, 2013). A participant reflected on the obstructive and potentially harmful encounters she had with nursing sisters in a unit despite the presence of an established relationship:

> "*We have built up a relationship with the sisters, the professional nurses that work in the units but we don't often find that they are willing to help us. So much of the information that we need we must get ourselves. Not that we mind because then we know what we need and that its accurate and so on but we can't even rely on them for little things*." (P07)

This interpersonal negativity seen in the behaviour of sisters in a unit might influence the job satisfaction of the clinical research nurse. In a professional context, negative relationships develop, since people are rarely in a position to choose whom they work with (Morrison & Nolan, 2007, p. 205). The social exchange theory hypothesises that people enter into relationships because of the rewards (benefits, fulfilled needs, and other gains) that such relations are expected to bring. The theory further states that when no benefit can be found from a relationship people will not enter into the relationship (Morrison & Nolan, 2007). When entering a unit, a clinical research nurse could use the principles of social exchange theory to ensure that nursing sisters in a unit would relate to her positively.

- **Feeling like puppets**

Feeling like a puppet describes a person whose movements can be manipulated by another human being who pulls its strings. How one responds to a circumstance beyond one's control, is analogous to feeling like a puppet. Once their competence improved, nurses feel like puppets that are released from such symbiotic strings (Duchscher, 2008, p. 431). A clinical research nurse emphatically expressed her feelings of powerlessness in her role:

> "*It's like you having to co-ordinator* [sic] *to run after them with a piece of paper, please sign, please sign! So, that makes it very frustrating. We do feel like puppets, like you know, we have to do all the work but we have none of the power. None of the, you know… all of the responsibility but no input and it is very frustrating. That I wish that they would give us as study co-ordinator* [sic] *with more power to sign off things that are not really… can't say not important, it is important, but that we are given a bit more power because we are also highly trained medical professionals.*" (P07)

The clinical research nurse potentially can overcome feelings of powerlessness by means of constructive self-talk that could possibly create room for her to innovatively empower herself (Rogelberg, Justice, Braddy, Paustian-Underdahl, Heggestad, Shanock, Baran, Beck, Long, Andrew, Altman & Fleenor, 2013, p. 185).

- **Time intensive continual training**

The Federal Drug Authority (FDA) draft in the United States of America, suggests that it might be necessary to implement alternative training and communication methods (teleconferences, webcasts, or online training modules) for providing and documenting continual, timely training and feedback, as well as providing notification of significant changes to study conduct or other important information (U.S. Department of Health and Human Administration, 2011, pp. 13-14). A participant described her frustrations with continual training:

> "*...you know, the Medicines Control Council and the FDA and they become so picky and some of the companies that we work with has become so picky and all the online training that we have to do. It's not enough for them that you did a GCP course; you have to do online GCP training for that specific company for*

three hours and it's… time is precious, you know. We have actual people outside so you know if... day after day online training and you are going to have to keep a record of training and it has to be written done [sic] *and you can't sign it off. The doctor has to sign it off that you did the training and it is becoming very frustrating*." (P07)

The challenge for the clinical research nurse when faced with time-intensive continual training is how she integrates the training with her learning goal orientation (LGO) and her performance goal orientation (PGO) mind set (Anseel, Beatty, Shen, Lievens & Sackett, 2013, p. 4). A possible strategy is to identify a feedback seeking behaviour model that can be incorporated into continual training (training is not isolated). Self-motivation could possibly facilitate the inclusion of time intensive training in already busy working days.

- **Lack of communication**

Communication is regarded by some as a phenomenon when two or more parties construct meanings during interaction (Leeuwis & Aarts, 2011, p. 24). Meanings come about and are actively constructed in a complex manner that is not neutral. Communication does necessarily bring people closer together or supports problem-solving processes but it could also escalate the lack of understanding, as well as the creation and reproduction of problems and conflicts (Leeuwis & Aarts, 2011, p. 25). A participant reflected on how the complexity of communication affected her as an individual in the team:

"*…communication, the lack of communication, you know, not supplying the next person with all the tools that he will need to do his job properly*." (P07)

The clinical research nurses' uppermost aim needs to be the understanding of one another's principles with the intent of working collaboratively, facilitating effective communication, and exchanging information effectively.

- **Increased demands related to monitoring and data capturing**

In clinical research studies, sponsors are responsible for monitoring patients' data and safety; however, this responsibility is often delegated to Clinical Research Organizations or Clinical Trials Units. These monitoring activities are regulated by or contained in ICH-GCPGood

Clinical Practice (Hutchinson, 2008, p. 23). A participant described the managing role of monitoring activities of a clinical trial:

> "*It's when the pharmaceutical company who is running the study will come and check that you are following the protocols and what's in your source information is the same as in the Case Record Forms and these days, we capture our information onto the computer. So, whether our source information from our paper source is the same as our computer electronic diaries*." (P06)

A participant further expressed her frustrations and challenges encountered due to increased monitoring visits:

> "*Well, because there is so much more paperwork, so there's a lot more monitoring visits and things like that." (P06)*

> *"It somehow… because the trials are getting more and more complicated, I think partly due to electronic case forms, the information that gets requested from us is a lot more than what it used to be. In the past when you have* [sic] *paper case record forms and in the past it was easier to split your time between practice* [sic] *work and clinical work and trial work and whereas the way trials are done now, I find it difficult to do clinical work and clinical trial work, you know, practice work and trial work because it's very difficult to apply your mind 100% to both. So, I prefer to do just the clinical trials because there's quite a bit these days*." (P07)

The hypothetical golden standard of clinical monitoring in practice is many on-site visits and a 100% data checking. It is particularly relevant to clinical studies with the highest participants' risk. However, clinical research nurses in the Southern Suburbs of Cape Town experienced that this golden standard is potentially applied more generally across all studies and contributes to feelings of increased work demands (Journot, Pignon, Gaultier, Daurat, Bouxin-Metro, Giraudeau, Preux, Treluyer, Chevret, Plattner, Thalamas, Clisant, Ravaud & Chene, 2011, p. 23).

3.2.3 Personal traits of the clinical research nurse

Figure 3.12: Theme 3: Personal traits of the clinical research nurse

3.2.3.1 Confidence

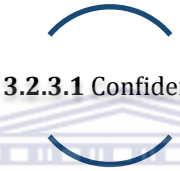

Figure 3.13: Category 10: Confidence

Confidence is defined as one's confidence and one's influence or abilities (Random House Kernermen Webster's College Dictionary, 2010). A participant emphasised the need for inherent self-confidence when working as a clinical research nurse:

"*So, like I said to you, you have to be very confident within yourself…*" (P01)

When individuals have greater self-confidence, they are more likely to engage in a given task, irrespective of their abilities (Noe, Tews & Marand, 2013, p. 328). All participants in this study had an almost inherent self-confidence, which may confirm their ability to engage in tasks that are outside of their original domain of nursing practice. Research shows that confidence levels can be increased by gaining appropriate knowledge and receiving effective feedback (Aoyama, Tamura, Ishikawa, Yada & Miyawaki, 2013, p. 508).

3.2.3.2 Determination

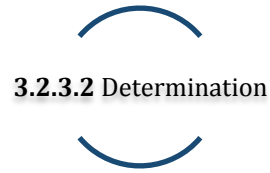

Figure 3.14: Category 11: Determination

The self-determination theory is a theory of human motivation that addresses such basic issues as personality development; self-regulation; universal psychological needs; life goals and aspirations, energy, and vitality; subconscious processes; the relation between culture and motivation; and the impact of social environments on motivation, behaviour, and well-being (Deci & Ryan, 2008, p. 182). The clinical research nurses' determination falls within the ambit of self-determination theory, since it is her intrinsic motivation and self-regulation that dictate her practice in nursing units. Participants confirmed their ability to withstand work demands and challenges through their self-regulatory mechanisms:

> "*…you have to be very determined because you can come across people who just won't allow you to do something…*" (P01)

> "*…So, I would rather plan something and try and finish it before I leave for the day and especially now with the ECRFs* [electronic case report forms] *and the amount of work. That is what we have to do otherwise, once you're behind, you're behind and then you need to do filing so that's the worst thing about…*" (P07)

It is possible that the self-leadership role of clinical research nurse requires the demonstration of high levels of self-determined involvement in her daily tasks and interactions. Self-determined involvement promotes openness rather than defensiveness and facilitates perspective taking, flexibility, honesty and authenticity, awareness of needs and support of close associates, and relational well-being (Knee, Hadden, Porter & Rodriguez, 2013, pp. 308-309).

3.2.3.3 Professionalism

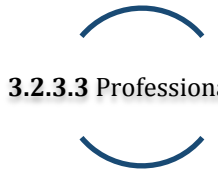

Figure 3.15: Category 12: Professionalism

Keeling and Templeman, (2013, p. 19) define professionalism as a state of mind and a way of thinking while emphasising the cognitive aspects of a profession. The typical characteristics of a professional allude to nurses' behaviour; such as autonomy and self-regulation, belief in public service, a sense of vocation, and accountability (Keeling & Templeman, 2013, p. 18).

Participants described their professional demeanour that resulted in positive interactions with other nursing staff:

> "*…but I think it's like with any team building you have to come with the same picture every time, you mustn't change, you must come and you must be professional…*" (P02)

> "*…if you are very assured of your professionalism and your role and your job, then it will filter through...*" (P01)

> "*I would go in there with a purpose, where* [sic] *the patient needed because of the research, you know. They needed an assessment or they needed blood taken or something like that and if one approach it through the head nurse and explains, I have not found any… my interaction has been very good on a very friendly basis. They have always been most willing and obliging*." (P04)

The values of a professional nurse in South Africa are described in the Code of Ethics of the SANC (SANC, 2013). The findings in this study indicate that the clinical research nurse emerges as a professional nurse who self-identifies with her professional values and allows these values to broadly impact decision making during her practice (in collaboration with patients, colleagues and other professionals) in nursing units.

3.2.4 Self-leadership behaviour

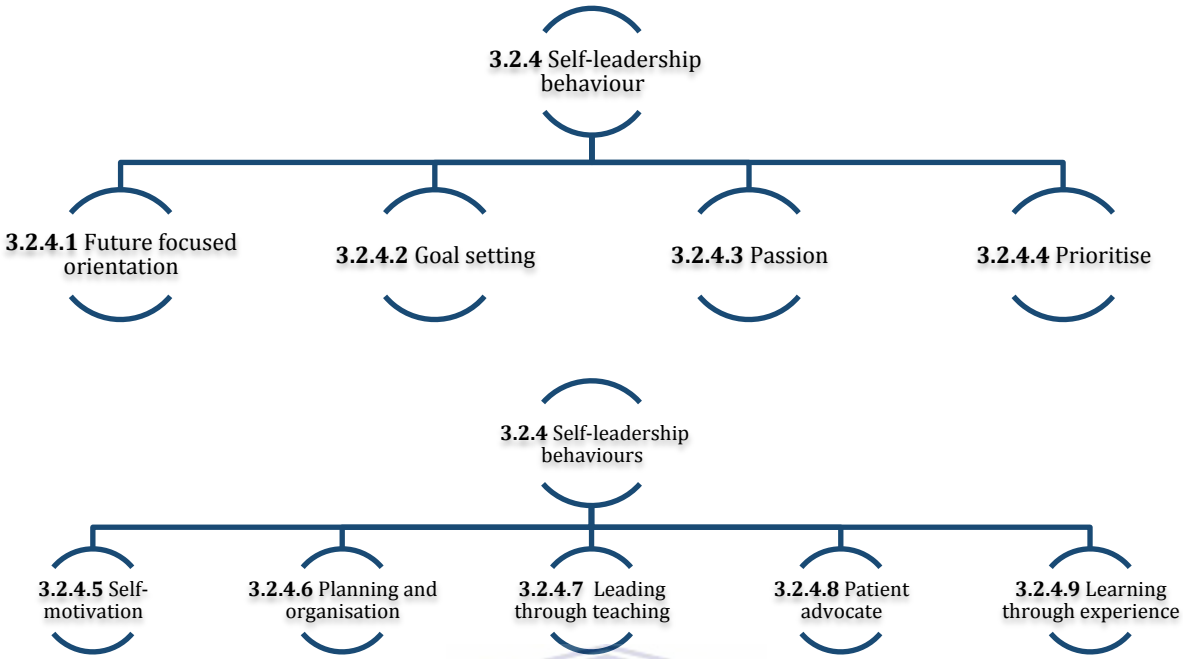

Figure 3.16: Theme 3: Self leadership behaviour

The behavioural self-leadership strategies incorporated in the self-leadership approach are self-management strategies; namely goal setting, self-monitoring, and self-reward (Unsworth & Mason, 2012, p. 235). The other self-leadership strategies that clinical research nurses also adopt, such as cognitive and emotional strategies are outlined in the relevant categories.

3.2.4.1 Future focused orientation

Figure 3.17: Category 13: Future focused orientation

Individuals who take cognisance of a future time perspective are inclined to persistently engage in future thinking and planning with the intent of ensuring that their present behaviour

aligns with future aspirations (Visser & Hirsch, 2014, p. 89). A participant mentioned the importance of confronting unfounded prejudices to facilitate better long term working relationships:

> "*I'm also loved in different areas and you I hope will start to respect me but I cannot be held responsible for your not greeting me but I understand it. I understand it hugely but you must look at me with a new eye and you must decide whether I, if you like me, you don't like me. I'm doing my job, you must come with an open heart… it took about a week, I think, and then suddenly I got, oh good morning, oh good morning and then I got yes please, if you wouldn't mind doing that, OK, I don't mind*." (P02)

Clinical research nurses possibly utilise behaviourally focused strategies to initiate difficult conversations in order to support her general role performance.

A participant described the importance of contextualising experiences in relation to your goals:

> "*Career-orientated: I want to do this and this is where I want to be, I want to gain experience for X, Y and Z. So, this is what I need to do to get there*". (P01)

Future focused orientation as an aspect of goal orientation is a behaviourally focused self-leadership strategy that leads to enhanced levels of general self-efficacy perceptions and subsequently serves to affect performance outcomes (Prussia, Anderson & Manz, 1998, p. 534).

- **Family**

The researcher chose to align with the perspective of *family* proposed by Levin and Trost (1992, p. 351) who state: "Our perspective is that we do not know what is meant by the term family". The term family has different meanings to different individuals and hence, individuals assign their own meaning to the concept. Participants commented on the interplay between family relations and work decisions:

> "*…I am family orientated; I need to do this for my family. So, I can't have a job where I am tied down twelve hours a day because that is not going to serve my purpose of dealing with the needs of my family…*" (P01)

"*…for me it's my family… at the end of the day. I want to ensure that they have a future and the thing is but for me it's like I can't work towards a future for my children if I am never there for them…*" (P01)

"*It's a very nice job, especially if you have a family and you don't want to work ward hours*." (P06)

Literature defines the family-relatedness of work decisions as the extent to which an individual's decision-making process and the course of action in the work domain are influenced by a family situation in order to maintain positive outcomes for the family (Greenhaus & Powell, 2012). The work situation e.g. demands and responsibilities, could have implications for the well-being of the individual's family (Greenhaus & Powell, 2012, p. 246).

Another participant described using the support she received from her family as a mechanism to help her cope with work stressors:

"*Well, I think if one has a stable private life, that helps you cope with all stresses at work and so on. So, I do try and switch off when I go home even though it is quite difficult*." (P07)

The clinical research nurse takes on the responsibility of self-influence to develop coping resources. These resources could have a relationship coping dimension and a skills coping dimension (Appel & Kim-Appel, 2008, p. 232). Positive family relationships as a coping resource are considered to consist of two constructs, namely cohesion (closeness) and flexibility (Appel & Kim-Appel, 2008, p. 232).

- **Career**

Social Cognitive Career Theory posits that person-environment interactions form learning experiences that, in turn, influence perceived confidence in one's abilities to perform career-related tasks and activities (i.e. career self-efficacy) and the types of outcomes one expects as a consequence of given career pursuits (i.e. outcome expectations). The theory asserts that career-related interests, goals, and choices develop from relevant self-efficacy principles and outcome expectations (Bakken, Byars-Winston & Wang, 2006, p. 93). A participant gave an account of her experience of taking ownership of her career in the clinical trial environment:

"*Especially the clinical trials, it feels like my baby so you know, I've cultured it, we've grown, we've figured things out, how things should work and I feel ninety per cent of it is mine …*" (P07)

Individuals' personal careers, as well as the future of organisations are shaped by effective leadership behaviour. Project ownership is a leadership behaviour that could facilitate career growth and work satisfaction (Ugurluoglo, Saygili & Ozer, 2013, p. 1).

- **Job**

Job satisfaction and the intention to remain in a particular career could affect nurse retention in various areas of clinical practice that are influenced by organisational, managerial, work-related, and individual determinants (Boyle, Miller, Gajewski, Hart & Dunton, 2006; Gilles, Burnard & Peytremann-Bridevaux, 2014).

A participant described how the diversity of her job responsibilities serves to influence her intent to stay:

"*…I find I have enough administrative duties, I have enough clinical duties, I have enough client interaction, not to make me feel like I am missing out. There is enough there for me to balance it out and still see like I am getting something… I am at a point where it is still interesting for me*." (P01)

Another participant simply said:

"*I just enjoy the job*." (P06)

The participant continued by reflecting on the enjoyment of the job in the midst of organisational changes in the clinical research industry:

"*Like the computer. I like it, I do, I like it very much. They've improved that over the years. At firs, the electronics weren't as good as they are now but they're nicer and it's very nice to sit on there and you just put a claim in you're not paging over and having these huge files and this sort of thing like this (shows huge file) to put it all in and you don't have to worry about, just making sure that as you've written, that it's gone through with one, two, three, or four pages and it*

hasn't gone onto the next page. you've forgotten to put your cardboard in, I like the electronic diary, the data capture..." (P06)

Job satisfaction has been closely linked to an individual's intent to stay in a particular job (Zangaro & Soeken, 2007, p. 445).

3.2.4.2 Goal setting

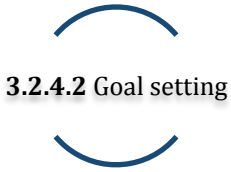

Figure 3.18: Category 14: Goal setting

An achievement goal approach (AGA) can be divided into mastery (learning) and performance goals. Mastery goals are aims that an employee seeks to either develop their competence, or to master a task. Performance goals, on the other hand, are those that an employee aims at to demonstrate his or her competence relative to other co-workers (Dysvik & Kuvaas, 2013, p. 413).

A participant described her tendency towards maximising her personal growth through setting goals as an opportunity to propel her towards a career that would best suit her needs:

"*I have set a goal for myself, not fixed in terms of time but a very loose goal where I want to see myself in ten years… I know doing research and doing this, getting this kind of experience is a stepping stone towards what I want to do at the end of the day...*" (P01)

This participant seemed to be a goal-orientated learning individual. Such individuals perceive their abilities as malleable and their know-how as contingent on expended effort. Hence, they are more likely to perceive life circumstances (e.g. work transitions) as career enablers rather than barriers (Tolentino, Garcia, Lu, Restubog, Bordia & Plewa, 2014, p. 41).

3.2.4.3 Passion

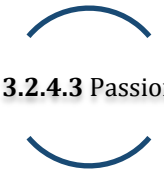

Figure 3.19: Category 15: Passion

Perrewe, Hochwarter, Ferris, McAllister, and Harris (2014, p. 146) describe work passion as an individual's emotional and persistent state of desire on the basis of cognitive and affective work appraisals that results in consistent work intentions. A participant described how diversity and patient interaction intrinsically motivate her passionate experience of her task:

> "*It's my passion for my work. You have to love what you're doing because you work on your own and your patients motivate you and your love of what you're doing. I mean your… the wanting to help, to actually what is so nice about it, is that you still have the contact with patients. you're not just a pen pusher; you can use your nursing training and yet there is diversity in your work. Every trial is different, every patient is different and most of all, I love the contact with the patients*." (P04)

For the clinical research nurse her work passion is based on affect, cognition and intention and efforts to improve her performance should be designed around this (Zigarmi, Nimon, Houson, Witt & Diehl, 2009, p. 320).

3.2.4.4 Prioritise

Figure 3.20: Category 16: Prioritise

Phillips and Bana e Costa (2007, p. 154) distinguish between two different forms of prioritisation, namely appraisal of options and constructing portfolios. Option appraisal is the process of arriving at a general hierarchy of several options in an area and constructing portfolios is an appraisal of options across many areas to find the best combinations of options for a given level of resources.

A participant verbalised her ability to process information in an orderly way in order to avoid repeating tasks:

> "*...so, I think once you then prioritise and rather do what is important first and try do it right the first time around and not do it in a cycle of repeating things…*" (P07)

Zhang and Feyen (2005) identify that the self-regulation processes of prioritising tasks are essential for successful work performances and for avoiding repetition (p. 1172).

3.2.4.5 Self-motivation

Figure 3.21: Category 17: Self-motivation

Motivation is broadly defined as something that moves people to take action (Ryan, Lynch, Vansttenkiste & Deci, 2011, p. 197)**.** A participant explained how easy she found it to motivate herself and to transform her negative experiences into more positive ones:

> "*Well, I knew I had to learn because there was no-one else. So, I mean that was… it was pretty easy to motivate myself because I mean I knew I had to know the stuff. So, I didn't really require motivation, you know. So, I did find it difficult but the PI didn't assist me, but I mean I had to accept that. It's probably the best way to learn anyway, you know*." (P05)

When people choose and master difficult tasks, their self-motivation is strengthened by mobilising their internal resources (Bledow, 2013, p. 22).

- **Independence**

Independence is the practical ability to provide care, exercise independent judgement, and self-governance in the scope of practice of registered nurse (Weiland, 2008, p. 345).

Participants described how the clinical research environment is well suited to their independent personalities:

> "*…but the one thing that I've always used to motivate myself from the word "go" is that I have an inherent personality flaw; I would say not to be dependent on other people…*" (P01)

> "*What makes me think I like independence? I like the time not within the nursing structure but I like my own level... you know, as long as I see my patients, do my work, I'm only answerable to myself and obviously whoever the sponsor is and the doctor and I think that's what moves me forward and...*" (P02)

> "*I like the challenge and I like working independently. I like being responsible for my own successes and my own failures*." (P03)

The role of the clinical research nurse potentially allows for high levels of independence. Literature purports the validity of an independent personality as an influencing factor that is likely to require higher autonomy as opposed to job activities that require little autonomy (Penney, David & Witt, 2011, p. 298).

3.2.4.6 Planning and organisation

Figure 3.22: Category 18: Planning and organisation

Planning is a basic management function that involves the formulation of one or more detailed plans to achieve an optimum balance between needs or demands and the available resources with the aim of structuring an entity in an orderly and functional manner in order to serve the best interest of the organisation (American Heritage Dictionary of the English Language, 2009). Participants described the detailed project management strategies needed in order to successfully do their jobs:

> "*...I think you need to, for this job, you need to be very particular and precise. You need to enjoy admin work and have that balance then of also patient relationship because you see your patients in all sorts of conditions*." (P03)

"*I've got certain systems that I use for planning. I believe that planning is your… one of your most important things*.". (P03)

"*I start thinking when I wake up in the morning. I love to plan my day, so I know I have to do X, Y, and Z and I won't go home until I've done what I've set out to do…*" (P07)

"*My phone's on and I make sure the patients understand that but having said that, they don't take advantage of it; they really don't. It's not that often that a patient will phone me. Occasionally they will; they will go to the doctor for some other complaint and they will have been told by me that they cannot have any… certain medications they can't have while they're on the study. Well, they'll phone me and say, can I have an antibiotic, or can I have this. I'm at the doctors and of course, that sort of thing is important or they will say they're in terrible pain. What can they do about it, or they've been very depressed sometimes and will phone me, or they need another change in their appointment. So those are the sorts of calls, but they don't take advantage*." (P04)

"*I think because there are certain things that need to be done on each visit and those are predetermined in the protocol and if one carefully follows what has to be done, the system of how it all operates or how what has to be done*." (P04)

Clinical research nurses should not be exempt from nurse leadership development, since literature regards them as individuals who have to develop their own leadership style and project management competencies. These competencies and leadership skills need to be enhanced, nurtured, and directed because the need for strong nursing leadership in all domains of nursing practice is an international mandate (Macphee, Skelton-Green, Bouthillette & Suryaprakash, 2012, p. 160).

3.2.4.7 Leading through teaching

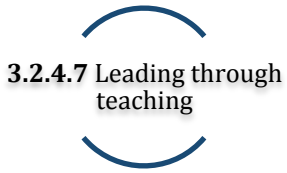

Figure 3.23: Category 19: Leading through teaching

Leading through teaching requires transformation. A transformational leader inspires by sharing the organisational vision of clear roles, effective teamwork / organisational structures, and providing feedback on individual / team performance. Transformational leaders enable members of staff to explore their professional practice that promotes a culture of learning and engenders commitment to give organisations a competitive advantage, since the most recent knowledge is transferred to practice (Halm, 2010, p. 377).

A participant reflected on the failure of more experienced nurses to teach by sharing her resolution to avoid territorial behaviour when interacting with junior staff members.

> "*…I think where we fail in nursing, is that we don't get our colleague and so I have resolved that I will never be territorial. If a junior member of the staff says can you come help me check this at lunch, I'll come because I think they have a terrible attitude with junior staff; terrible and so I do lead by teaching*." (P02)

Research supports this participant's perception that junior staff members are able to learn through mentorship and teaching but currently due to various demands, such mentorship and teaching is lacking (Ballem & MacIntosh, 2014). A natural leader explains to followers and teaches them to develop the competence needed to perform their everyday nursing practice (Valiga & Grossman, 2008, p. 199). In her self-leadership role, the clinical research nurse epitomises a transformational leader in her willingness to allow for a culture of learning. This willingness is amplified by her choice of career.

3.2.4.8 Patient advocate

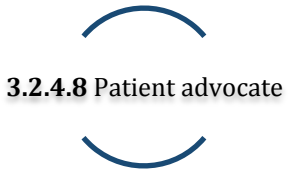

Figure 3.24: Category 20: Patient advocate

Patient advocacy is the process of informing patients adequately for them to make knowledgeable decisions and to support them after they had made their decisions (Graham, 1992, p. 149). A participant had a particular view about the importance of patient advocacy in clinical research nursing:

> "*…I think, I see my role as a study nurse and I also see myself as the advocate of the patient in a trial… so, I think one of my… another of my important roles is actually to be the advocate of the patient and say, listen. Do you actually understand what's going on here…*" (P02)

The abovementioned participant indicated how the strategy of self-monitoring enabled her to be an advocate for the patient. This role she assumed by her own volition as a clinical research nurse. Ellis (1992) cites Murphy and Hunter (1984) who have stated: "The goal of the nurse is not to receive gratification from other health care professionals but rather to help the patient obtain the best care even if it means going against hospital admin and other health care professionals".

3.2.4.9 Learning through experience

Figure 3.25: Category 21: Learning through experience

Learning through experience can be compared to *active learning*, *informal learning*, and *work place learning*. Informal learning is a process initiated by an intent to learn, followed by experience and action, feedback seeking, and reflection (Noe *et al*., 2013, p. 283). A participant explained how stressful her *hands-on* learning experience was:

"*...I never ever had any formal training. I had an understanding of it through the GCP course but certainly not any experience and it was a hands-on learning process*." (P04)

"*Because it is stressful, because it is a very… it's very meticulous work and you can make real mistakes which is what you want to avoid, obviously*." (P04)

The behaviour focused strategy of *self-punishment* (awareness of *real mistakes*) could facilitate the meticulous work that clinical research nurses need to perform. This supports the development of the skills needed to meet the quality and productivity demands of high paced clinical research. The success and effectiveness of a clinical research nurse's learning is possibly associated with the adoption of behaviour focused strategies that establishes a paradigm where work and learning are inseparable, therefore, learning becomes embedded in her daily processes (Cook & Smith, 2004, p. 35).

3.3 CONCLUSION

This chapter presents the themes and data categories that have emerged from the data analysis. The aim of this presentation is to capture the essence of each participant's experience.

CHAPTER 4
CONCLUSIONS, GUIDELINES, AND RECOMMENDATIONS

4.1 INTRODUCTION

The second objective of this study was to develop guidelines for clinical research nurses with clear instructions for their self-leadership role in nursing practice in the southern suburbs of Cape Town. A shift towards risk and adaptive forms of monitoring means the roles and responsibilities of the clinical research nurse will expand; it makes the need for assistance with self-leadership an imperative ingredient of these guidelines. Self-leaders exemplify effectiveness in their behaviour and thoughts strategies.

4.2 CONCLUSION

The researcher concluded that clinical research nurses in the southern suburbs of Cape Town were acting independently, whilst ensuring collaborative partnerships either on site or as a member of a virtual team. Such a dynamic, complex role required self-leadership. In accordance with social cognitive theory, the researcher believed that human behaviour can be comprehended, analysed, and changed.

4.3 GUIDELINES

The researcher developed the guidelines according to the categories that had emerged from the data (Table 3.1). Some of the categories were grouped together in formulating the guidelines.

Table 4.1: Themes and their guidelines

Theme	Guidelines
Overcoming the initial tedious and daunting phase	**Guideline 1**: The clinical nurse should promote positive perceptions among staff members **Guideline 2**: Sell the idea, benefits, and vision of the project **Guideline 3**: Practise self-observation and positive self-corrective feedback to build trusting relationships **Guideline 4**: Be strategic when forming collaborative partnerships

Work towards collaborative actions	**Guideline 5**: Use constructive thought patterns and behaviour focused strategies to invest time in assessing, understanding, and maintaining quality and integrity in the clinical research project **Guideline 6**: Use natural reward strategies to apply knowledge and skills **Guideline 7**: Use natural reward strategies and behaviour focused strategies to seek out and focus on new and positive experiences **Guideline 8**: Demonstrate self-motivation when faced with negative experiences
Recognise personal traits of the clinical research nurse	**Guideline 9**: Be self-confident in performing research activities when visiting nursing units **Guideline 10**: Demonstrate self-determination in the face of complex problems
Self-leadership behaviour	**Guideline 11**: Make goal setting part of your everyday activities through maintaining an achievement goal approach **Guideline 12**: Demonstrate self-regulatory behaviour that is motivated by work passion **Guideline 13**: Demonstrate the ability to prioritise appropriately **Guideline 14**: Learn what self-motivation is and how to use it **Guideline 15**: Harness behaviour-focused strategies to ensure planning and organisation of research activities take place throughout the lifespan of the project **Guideline 16**: Be a transformational leader who leads through teaching **Guideline 17**: Demonstrate professionalism and excellence by using self-monitoring to sustain one's ability to be a patient advocate **Guideline 18**: Be committed to life-long learning

4.4 OVERCOME THE INITIAL TEDIOUS AND DAUNTING PHASE BY BUILDING TRUSTING RELATIONSHIPS WITH NURSING STAFF

When starting a career as a clinical research nurse, the initial phase could be tedious and daunting. A clinical research nurse may initially experience feelings of isolation, discouragement, and uncertainty while possibly encountering nurse-to-nurse hostility, anxiety, and misperceptions by study members of staff about her competence. These experiences are possibly based on nursing staff viewing the clinical research nurse as an "outsider", taking on new responsibilities associated with her change in role, and becoming a member of a virtual team (often the sponsor is not in the same location). She is further faced with the challenge that daily tasks might likely be tedious and repetitive.

4.4.1 Guideline 1: The clinical nurse should promote positive perceptions among staff members

When visiting a nursing unit for the first time, clinical research nurses could be confronted by negative perceptions. The self-leadership role of the clinical research nurse requires an ability to influence other people to perceive clinical research in a more positive manner. While seeking to understand human motivation, it is important that clinical research nurses remain mindful of the realness of human perceptions and how it influences their actions (Lopez & Willis, 2004, p. 727).

Guideline 1 requires the clinical research nurse to consider the following actions:

- The resistance and hostility of nurses could dissipate when the clinical research nurse builds trust by putting into action what she says.
- The clinical research nurse could possibly use an assertiveness strategy to create a pleasant working relationship. At the same time, the clinical research nurse needs to appease the nursing staff by emphatically explaining that the research would not add to their workload (Roberts, 2009, p. 958). One could use assertive discretionary transparency to overcome perceptions about increased workload by:
  - Clear and concise communication in collaboration with the unit manager; and
  - Introduce the research study needs, study-specific research procedures, and educate staff members in the unit about the study.
- Think of ways to kindle effective interaction amongst people, such as:
- Show appreciation for the work that staff members do in the unit and perform small nursing tasks to demonstrate that the clinical research nurse is part of the team.
- Be enthusiastic about the scope of your project and schedule a staff session with the unit to share interesting findings.
- Demonstrate self-talk practically by staying focused on positive attributes by means of constructive self-talk.
- Constructive self-talk is self-analysing, well grounded (principle-based and not feeling-based), and has an encouraging orientation (optimistic / opportunity thinking).
- An inner dialogue enables the clinical research nurse to either manage her practice, or to start a new project (Rogelberg *et al*., 2013, p. 186).

4.4.2 Guideline 2: Sell the idea, benefits, and vision of the project

The clinical research nurse is required to find ways to promote the ideas, benefits, and vision of the project to nursing staff in a particular nursing unit. The idea of a bench-to-bedside project (an endeavour to transpose basic scientific findings into therapeutic interventions) is potentially foreign to nursing staff. A limited understanding of clinical research could affect the way in which the clinical research nurse is able to conduct research related activities in the nursing unit. Therefore, a choice needs to be made to promote the idea of the project to nursing staff at the clinical site, which potentially would results in the cooperation needed for the successful completion of a project.

Guideline 2 requires the clinical research nurse to consider the following actions:

- Focus on assertive communication. Assertive communication is the clear expression of opinions and feelings that strongly advocate for an individual's rights and needs without violating the rights of other people. Self-reflection is needed to establish why assertiveness is needed for one to achieve certain goals. Communication should encompass:
  - Introduction to the nursing manager of the unit;
  - Asking permission to introduce nursing staff members to the concepts of translation and clinical research; and
  - Whilst speaking to staff members about these concepts, use the opportunity to share the background to the project.
- Explain the need for more locally relevant research to inform local practice and that the staff members in the unit have an invaluable contribution to make in terms of local application. Nowadays, it is acknowledged in health care settings that clinicians and managers should base their practice and decision making on evidence. The integration of contextual evidence allows research to be implemented in specific settings (Bowen & Graham, 2013, p. 3).
- Paint the bigger picture (context and background) of the project to the nursing staff.
- Provide concrete direction and information on study procedures and assist nursing staff to grasp that their cooperation would not add to their workload.
- Provide feedback about nurses' conduct during research related activities and remind them about benefits of the project.

- The respect of nursing staff who have accepted the contribution of the project could be used to convince the sceptical ones. Two types of respect could be used at work; appraisal respect that is based on individual characteristics and recognition respect that is based on being human and having rights (Grover, 2014, p. 27).

4.4.3 Guideline 3: Practise self-observation and positive self-corrective feedback to build trusting relationships

Interpersonal skills are those aspects of the human personality that allow us as human beings to construct relationships. The clinical research nurse needs to practise self-observation with the aim of determining when she needs to change, enhance, or terminate her interpersonal skills. Trusting relationships are created by conveying to other people the principle that they will meet set expectations and are dependable. Such trusting relationships form part of a high quality connection (Dutton, 2014). The establishment of high quality connections assists with acquiring access to information. Furthermore, these connections strengthen an individual's ability to endure stress and hardship and / or to tackle new and more demanding challenges (Dutton, Morgan-Roberts & Bednar, 2010, p.266).

Guideline 3 requires the clinical research nurse to consider the following actions:

- Use self-observation to focus on:
  - Being trustworthy, consistent, and dependable. These attributes create an optimistic environment that establishes the context for forming trusting relationship. When one performs small nursing tasks in a health care unit, being consistent demonstrates authenticity in a practical way. The social cognitive theory states that people learn behaviour and consequences of behaviour vicariously. This dynamic enables these individuals to learn by simply observing people around them and assessing their performance (Bryant & Kazan, 2013).
  - Working collaboratively and harmoniously with nursing staff.
  - Monitoring interactions with staff members to determine potential barriers to trust.
  - Considering how as a professional nurse working in research, one is able to motivate patients to change behaviour. One can also motivate staff members to assist with performing daily tasks in a nursing unit.

- Use self-corrective feedback to facilitate:
  - Continual demonstration of the principle that the interaction with nursing staff and patients requires respectful treatment. Acting respectfully is an important perceptual part of human interaction, therefore, it strongly influences target individuals' perceptions of the way in which they are treated and their assessment of the motivations of such treatment (Grover, 2014, p. 44).
  - The practice of candour, transparency, and flexibility when interacting with staff members in a unit.
  - Assertive communication when initiating difficult conversations when study activities conducted by nursing staff in a unit are not working according to the project plan; acknowledge that everyone can make a mistake and see these discussions as an opportunity to build authentic relationships with staff.
- Use self-observation and positive self-corrective feedback wisely. Based on self-observation (what do I need to change, enhance, or terminate to build a relationship of trust), the following steps can be taken:
  - Return to the basics; i.e. what it means to be open, respectful, honest, and humble).
  - Practise openness during verbal and non-verbal communication.
  - Acknowledge that everyone can make a mistake.
  - Build good relationships with staff members, since the assistance they give you depends on it.

4.4.4 Guideline 4: Adopt a strategic approach when forming collaborative partnerships

Successful collaborative partnerships are the foundation on which high quality clinical research is built. Such partnerships are relationship-centred in their practice and create a social system where information is processed, discussion occurs, and action is taken. A collaborative partnership between stakeholders requires the equal sharing of risks, responsibilities, resources, and rewards of collaborative efforts (Himmelman, 2002, p. 3).

Guideline 4 requires the clinical research nurse to consider the following actions:

- Negotiate while building relationships to reach desired patient outcomes. When one needs to take a patient's blood pressure for a study, offer to also take blood samples. This would decrease the workload of the staff while saving the patient's time.

- Demonstrate helpful behaviour, since it potentially emphasises the value of cooperation and facilitates positive work relationships. In general, this will lead to effective task performance.
- By applying the actions described in Guideline 2, determine the expectations of nursing staff and identify one or two staff members in a nursing unit with whom one could liaise constructively.
- Be sensitive to different cultures and develop workable cost-effective solutions for mitigating language barriers (Crockett, 2013, p. 363).
- The self-leadership strategy of mental imagery could be used to visualise collaborative partnerships that are based on relationship-centred practice. Mental imagery is the ability to symbolically transpose an experience to virtual behaviour that is similar to real experiences. Mental imagery allows one to see the outcome that should include the clinical research nurse as a member of the health care team. One could construct images about one's assistance to increase staff performances while being involved in research related tasks, such as:
  - While liaising, visualise a relational environment that encourages questions and conversations.

4.5 WORK TOWARDS COLLABORATIVE ACTIONS

The research nurse should aim at facilitating collaborative action. The relationships that a clinical research nurse is required to create when visiting nursing units develop over time, is enhanced by self-leadership, and results in collaborative action. In relation to self-leadership, the clinical research nurse is most likely aware that the maintenance of quality which a viable and safe project depends on requires the existence and implementation of shared leadership and strategic alliances.

The practice of constructive self-talk dialogues, the development of constructive thought patterns, and the use of natural rewards allow the clinical research nurse to identify opportunities for shared leadership, strategic alliances, and treating other role players as equals. Such a strategy creates a chain of positive behaviour in the midst of hostile or obstructive circumstances that could easily become obstacles. Shared leadership is a simultaneous, continual, and mutual process of influence in a team, which embraces the evolving encouragement of official and unofficial leaders in a team. The aim is to fully develop and empower all role players in a health care team (Pearce & Manz, 2005, p. 134).

A strategic alliance recognises that interdependent circumstances exist in a nursing unit and relationships are formed with this interdependence in mind.

4.5.1 Guideline 5: Use constructive thought patterns and behaviour focused strategies to continually invest time in assessing, understanding, and maintaining quality and integrity of a clinical research project

This guideline was developed using category four and five of the data analysis (Table 3.1). Constructive thought pattern strategies can help the clinical research nurse to identify dysfunctional cognitions, are designed to facilitate the management of cognitive processes and influence thinking patterns through self-analysis, imagining positive outcomes and positive self-talk (Hauschild & Konradt, 2012, p. 147). Behaviour-focused strategies on the other hand referred to specific behaviours that focus on self-assessment, self-reward, and self-discipline (Lee, Lee & Kim, 2007, p. 166). These strategies require that an individual enhance or modify their behaviours, doing a self-analysis to find long-term goals, recognizing and self-applying motivational rewards, lessening self-punishment patterns, and executing desired behaviours (Lee, Lee & Kim, 2007, p. 166). The clinical research nurse over time can learn how to identify dysfunctional cognitions which could hinder one from prioritizing quality and integrity.

The clinical research environment has moved to a point where the next revision of {ICH - GCP E6 (R2)} has been proposed by the International Conference on Harmonisation steering committee (ICH, 2014). Such a proposal serves as a reminder of the ever changing nature of the clinical research regulatory environment. The challenge of such an environment for the clinical research nurse is how does one assess, understand and maintain quality in the midst of such flux. Firstly, while definitions of quality may vary based on regulatory environments, the integrity with which a professional nurse in clinical research conducts her practice should remain the same. To maintain this integrity and to adapt and address changes in regulatory quality demands certain self-leadership strategies maybe utilised by the clinical research nurse.

Guideline 5 requires the clinical research nurse to consider the following actions:

- Allow moral integrity (personal ethics) to guide the “how” and the “why” of one’s practice.
- Use constructive thought patterns to:

- recognise and acknowledge the interdependent nature of tasks in a unit.
- imagine a social system for processing information that will result in discussions and actions in the nursing unit (build collaborative partnerships).
- use positive self-talk to construct thoughts that focus on what one can do, to be the best that one can be. Such a mind-set enables one not to shy away from helping and teaching other people while one's thinking acknowledges that the quality of a project depends on the cooperation of all members of staff.
- construct your dialogue with the unit manager to convince the unit manager that the integration of study follow-up visits into routine care would be mutually beneficial, i.e. proper follow-up might prevent the loss of information.
- use behaviour focused strategies to:
  - demonstrate shared leadership. Bear in mind that shared leadership is part of the alliance formation process (this includes constructive liaison that is emphasised in Guideline 4).
  - practise professional nursing accountability by taking responsibility for one's nursing judgements, actions, and omissions, since these professional expressions relate to life-long learning. Maintain competency and uphold both quality patient outcomes and standards of the profession while being answerable to those people (such as patients, the principal investigator, and nursing staff members in a nursing unit) who are influenced by one's nursing practice.
- ensure that one maintains a positive outcome by addressing training needs. Different levels of research, knowledge, and experience among team members, necessitate training of the team (Kelly & Ahern, 2009, p. 911).
- demonstrate a positive work ethic by self-analysing ones' principles and values. Based on one's self-analysis, one ought to challenge oneself to display:
  - Integrity in what one does.
  - Honesty in one's responses.
  - Responsibility and accountability for tasks completed.
  - Self-reliance in an environment of limited resources.
  - Self-management when one is strained.
  - Self-esteem in the midst of feelings of subjection.
  - Independence when advocating for patients' needs and rights.
  - Prudent when interacting with staff members.

- Acceptance of authority whilst striving for success (achievement orientation), understanding that one's general goal is to have a more enjoyable or financially rewarding life.

- Use self-assessment, self-discipline, and self-reward to renew contact with study participants. (Set aside previous experiences and emotions while creating dialogue that is professional, caring, and respectful).
- The recruitment processes of study participants as part of the role of a clinical research nurse should include:
  - information sessions with stakeholders;
  - an explanation of the informed consent process;
  - accurate data collection;
  - completion of data entry; and
  - supervision of fieldworkers and coordination of the research team to achieve the required quality and integrity.

4.5.2 Guideline 6: Use natural reward strategies to apply knowledge and skills

The clinical research nurse can use natural rewards strategies to apply her knowledge and skills. For the purpose of these guidelines, the researcher regards natural rewards strategies as inseparable from natural rewards self-management. Natural rewards self-management as purported by Lee and Turban (2010, p. 2267) is defined as a positive practice that should help people to achieve success in both educational and work contexts. The implementation of self-management creates environments that are conducive for the active revision of tasks through perceptual or physical means. As a professional nurse, the clinical research nurse is able to integrate her professional attributes of knowledge, skills, judgment, values, and principles within all contexts.

Guideline 6 requires the clinical research nurse to consider the following actions:

- Integrate knowledge, skills, judgment, values, and principles gained by practising as professional nurse and the role as a clinical research nurse simultaneously to experience the natural rewards of competence.
- Use the confidence gained from application of professional nursing competence to perform new tasks associated with the role of a clinical research nurse.

- View growth as a clinical research nurse as a natural reward for self-management that augments self-control and task responsibility.
- Design one's work and work environment in such a way that it takes full advantage of the intrinsic meaning and enjoyment derived from a task (Unsworth & Mason, 2012, p. 235).

4.5.3 Guideline 7: Use natural reward strategies and behaviour-focused strategies to seek out and focus on new and positive experiences

For a clinical research nurse, professional and personal growth can potentially be facilitated by focusing on positive emotions and finding ways of being engaged at work. Self-managed individuals are engaged at work and are associated with task performance that increases perceived competence, self-control, and task responsibility (Breevaart, Bakker & Demerouti, 2014, p. 31). Behaviour-focused strategies refer to specific behaviour that focuses on self-assessment, self-reward, and self-discipline (Prussia *et al*., 1998, p. 524).

Guideline 7 requires the clinical research nurse to consider the following actions:

- Be on the lookout for new and positive experiences at work that will enhance one's enjoyment of the job.
- Use feedback as a behaviour-focused strategy to find opportunities that add to one's knowledge and improve one's performance.
- View interactions with patients as a natural reward; make these interactions meaningful and enjoyable.
- Gain knowledge and skills by engaging with other subject experts with the aim of gaining the tacit knowledge one needs in order to perform a job more efficiently.
- See opportunities for paid international travel as a reward for one's skills and choose to maintain one's career focus whilst travelling (Petrick & Huether, 2013).
- View the blended working environment as an opportunity to focus behaviour on task completion (Scott, 2005, p. 683). For example, when one needs to invest more time on a given day, remember that the opportunity of flexible working hours is one's reward.

4.5.5 Guideline 8: Demonstrate self-motivation when faced with negative experiences

A genuine understanding of self-efficacy is the cornerstone of self-motivation. Bledow (2013, p. 17) defines self-motivation as the actual, self-initiated engagement with cognitive and behavioural resources. Self-motivation is not based on a belief in one's capabilities in response to demanding situations. The clinical research nurse needs to identify obstructive and potentially harmful encounters. Once these possible obstacles have been identified, one could use constructive though patterns to address their impact.

Guideline 8 requires the clinical research nurse to consider the following actions:

Use constructive thoughts (Guideline 5 provides a definition) to conquer feelings of subjection. Creative empowerment requires a reinterpretation of negative feelings. Disempowering regulatory structures do not take into consideration the competence of a clinical research nurse as registered health professional. However, it does influence a clinical research nurse's experience of subjection. At the time of this study, no potential changes to these regulations were envisaged. Informal suggestions have been adopted in order to mitigate these negative experiences.

- Contextualise time-intensive continual training in the framework of one's learning and performance goal orientation. For example, identify a feedback seeking behaviour model and integrate continual training into this model; this ensures that the training does not happen in isolation and forms an integral part of the general goal.
- Use positive scripts instead of futile ones when faced with communication challenges (Table 4.2).

Table 4.2: Example of ineffective versus positive scripts

Positive Script	Ineffective Script
I am a competent nurse; I am up to this communication challenge.	I can't do this; I am just not good enough for this job.
If I can lead myself, I can lead others.	I am a doer not a leader.
I have the capacity to learn how to get the job done right.	I can't get the job done right.

Practise desired goal orientated behaviour when faced with increased demands in work related situations.

4.6 RECOGNISE PERSONAL TRAITS OF A CLINICAL RESEARCH NURSE

Category 12 (professionalism) of the data analysis, forms part of this section. The researcher is of the opinion that the trait of professionalism should assist with recognising and implementing other important traits of clinical research nurses, since it forms a conduit for the development and application of such traits. The discipline of nursing is accompanied by an ethos of professionalism that is based on a guiding code of ethics. In South Africa, the Code of Ethics for Nursing Practitioners in South Africa (SANC, 2013) provides guidance for the professional conduct of nurse practitioners. As a professional nurse who is often required to practice independently, the clinical research nurse should refer to the code of conduct when deciding which personal traits would enhance her professional demeanour.

4.6.1 Guideline 9: Be self-confident in performing research activities when visiting nursing units

Confidence refers to one's strength of principle but does not necessarily specify what the certainty is about (Bandura, 1997, p. 382). The clinical research nurse reflects more than mere confidence; her confidence is based on her competence as a professional nurse. That is why a clinical research nurse develops into an example of self-confidence that is rooted in self-efficacy. Self-confidence represents an individual's principles in relation to his or her personal abilities and is viewed as a process that includes an individual's assessment of personal self-efficacy (Ross, 2014, p. 307). For a clinical research nurse, this self-confidence is an affirmation of her capability and strength of principle while practising in nursing units and it is based on one's competence as a professional nurse (Bowman, 1999, p. 559). A self-confident person believes that they are capable of achieving while remaining cognisant of the limits to the scope and depth of one's capacity to achieve. Self-confidence evolves over time as one learns from confronting and successfully conquering challenges (Ross, 2014, p. 307). The confidence one observes in a clinical research nurse evolves gradually and experientially to take on an inherent form. Self-confidence could also be built through self-imagined actions.

Guideline 9 requires the clinical research nurse to consider the following actions:

- Create a self-confident mental image during planning of new tasks and in the wake of working with new nursing staff members irrespective of the difficulty of the task with the aim of facilitating a positive outcome.
- Use the self-efficacy that originates from the image of oneself as a competent professional nurse to create a mental image of a competent clinical research nurse.
- Develop a learning goal propensity towards tasks with a view of receiving feedback from collaborative partners that would result in a gradual increase in confidence while time passes.

4.6.2 Guideline 10: Demonstrate self-determination when faced with complex problems

The clinical researcher nurse should be self-determined to solve problems related to complex, difficult, or important tasks. Complex and difficult tasks require self-motivation and sustained effort over a period of time. The core constituents of self-determination and its processes are goals and actions. That part of the motivational system is responsible for dynamically selecting actions or action sequences to regulate internal conditions; e.g. biological needs and learned motives (DeShon & Rench, 2013, p. 243).

Guideline 10 requires the clinical research nurse to consider the following actions:

- Create space for providing perspective-taking when managing staff of varying competencies. Perspective encourages the development of novel ideas that are useful (Grant & Berry, 2011, p. 73). This entails avoiding regimented behaviour and treating each member of the core team as an individual who has unique needs.
- Demonstrate flexibility in the execution of tasks. Flexibility allows team members to function to the best of their ability in a dynamic project environment (McComb, Green & Compton, 2007, p. 293).
- Have a mature response to your participates by avoiding emotional outbursts.
- Be flexible and accept that on a particular day things might not happen according to the plan and allow the planned activity to take place on another day.
- Allow a flexible attitude to facilitate the development of creative ways of addressing similar problems in future and for contingency planning purposes.

- Be an honest and authentic person during your daily work performance. Authentic behaviour proposes the promotion of positive and effective relationships that improve team functioning and productivity (Hannah, Walumbwa & Fry, 2011, pp. 772-773).
- Be friendly to and greet all nursing staff whenever one visits a unit.
- Advise the nursing staff about a particular procedure, e.g. the way in which the blood pressure of a participant needs to be taken for a research study. Remain consistent by not having a change of heart the next time a procedure needs to be repeated for the same study. Stability in performing daily activities is a practical way of strengthening authenticity.
- Develop an awareness of the core team members' needs, support them and teach them how to take a close interest in their and one another's wellbeing. Such an approach supports suitable coping mechanisms despite a highly pressured environment.

4.7 UTILISE SELF-LEADERSHIP BEHAVIOUR TO EMPOWER ONESELF WITH THE AIM OF MAINTAINING A FUTURE-FOCUSED ORIENTATION

The future-focused orientation of the data analysis (Category 13) underpins the daily practice of a clinical research nurse. The concept of a future-focused orientation for the clinical research nurse is not an abstract one. From the onset, the role of clinical research nurse includes an awareness of timelines (Schuitema, Peetsma & Van der Veen, 2014, p. 1). One moves from the security of a permanent ward / hospital based working environment to the insecurity associated with contract work, with an understanding that one's future employment depends on effective performance. To grasp this concept of constant efficacy, one needs to be empowered. Empowerment refers to one's effort that enables another person to act (Chandler, 1986, p. 6). Earlier, the researcher mentioned the initial negative aspects of a future-focused mindset. It should enable the reader to view a future-focused orientation as a clinical research nurse's gradual transition over a period of time. It is part of the empowerment process that includes self-efficacy and a desired future frame of mind. Coping strategies may include: (i) confront the unfound prejudices of staff members (have a long-term view about working relationships); (ii) contextualise challenging experiences that may occur, such as a conflict situation; and (iii) define, understand, and develop self-efficacy in one's daily duties. Understand how a future-focused orientation would enhance one's self-efficacy and assist with mitigating a heavy workload (Moen, Lam, Ammons & Kelly, 2013, p. 79).

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4.7.1 Guideline 11: Make goal setting a part of your everyday activities through maintaining an achievement goal approach

Use project ownership as the basis for establishing a set of general goals. These goals need to be value-based and closely aligned to personal goals. The achievement goal theory postulates that people are goal orientated, and want to obtain certain achievement or influence their social environment (Moreno, Cervello & Gonzalez-Cutre, 2010, p. 390). Clinical research nurses could implement these two approaches in order to achieve their goals.

Guideline 11 requires the clinical research nurse to consider the following actions:

- Be task-orientated through a mastery (learning) goal focus and choose to develop competence / mastering of tasks on a daily basis.
- Set goals every day to optimise personal growth. Goals are meant to guide daily decision making while understanding that the achievement of these goals requires additional effort, since they are often multi-layered and outcome driven.
- View the setting of goals as an opportunity to facilitate career development.
- Trust that one has the career potential to develop beyond the level of a clinical research nurse.
- Have long term goals, as these goals are important elements of job satisfaction and professional well-being.

4.7.2 Guideline 12: Demonstrate work passion

A clinical research nurse views work passion as dependent on one's emotional and persistent state of desire. This state is influenced by affective and cognitive appraisals and influences, and efforts to improve performance (Perrewe *et al*., 2014). Work passion is partly intrinsically motivated. Intrinsic motivation is defined as the carrying out of an activity for its inherent satisfaction rather than for some arbitrary consequence (Ryan & Deci, 2000, p. 55). The notion that clinical research nurses are intrinsically motivated is one of the golden threads of this study. Constantly, the essence as described in the analysis has demanded that the researcher acquire an understanding of what motivates a clinical research nurse.

In order to represent the role of a clinical research nurse, one should not only assign credit to the experience of perceived competence (or self-efficacy) but also acknowledge that behaviour needs could be self-determined (Ryan & Deci, 2000, p. 58). The effects of a

positive emotional impact on an individual's cognitive processing are assumed to be modulated by the intensity of motivation. Studies show that the positive affect of low approach motivation broadens attention and cognitive scope whereas the positive affect of high approach motivation has the opposite effect. This theory is relevant to a clinical research nurse during her practice because internally there is something keeps on driving her (Liu & Wang, 2014, p. 1116).

Guideline 12 requires the clinical research nurse to consider the following actions:

- Demonstrate desired goal orientation behaviour that is based on work passion, e.g. working according to a time schedule.
- Focus on self-empowerment and stay abreast of the latest trends in the field of clinical research through knowledge management.
    - Act on one's inherent interests, since they are growth opportunities and would most likely increase one's knowledge and skills.
    - Aspire to develop new competencies to accomplish something new (Gable & Harmon-Jones, 2010, p. 599)
    - During pursuit of a new goal, e.g. learning a new competency, a clinical research nurse could have a positive motivating influence on practice (Savaya, Altschuler & Melamed, 2013, p. 437).
    - Do not become distracted by irrelevant information and stay focused on achieving desired goals.

4.7.3 Guideline 13: Demonstrate how to prioritise appropriately

Daily prioritisation in in the clinical research environment is needed to avoid the duplication of tasks.

Guideline 13 requires the clinical research nurse to consider the following actions:

- Start out by learning how to use positive influence or a natural rewards strategy to prioritise tasks.
- Practise the appraisal of options available, which encompasses a comprehensive enumeration of several options in an area. This can be used to assist one to decide what task needs to be completed first.

- Facilitate the construction of portfolios of work. These portfolios could be used when numerous tasks across various aspects of the clinical research study require the input of the clinical research nurse.
- Use self-awareness to monitor self-control with the aim of prioritising time for every task. Ego depletion happens when people are temporarily less successful at exercising self-control. Potentially, ego depletion causes a shift in motivation with the result that emotions related to 'have-to' goals are dampened (Inzlicht, Schmeichel & Macrae, 2014, pp 127, 131). Self-awareness assists one to avoid a severe form of ego depletion, since an awareness of severe ego depletion requires one to access either external or internal motivation with the aim of successfully performing a 'have-to' task (Inzlicht, Schmeichel & Macrae, 2014, p. 131).

4.7.4 Guideline 14: Learn what self-motivation is and how to use it

In response to demanding situations, self-motivation refers to the actual, self-initiated implementation of cognitive and behavioural resources rather than relying on perceptions of one's capabilities (Bledow, 2013, p. 17).

Guideline 14 requires the clinical research nurse to consider the following actions:

- Develop an internalised understanding of how to motivate oneself with the aim of performing positively.
- Use one's self-regulatory processes to propel one forward to a desired future outcome. Propulsion requires high levels of independence. Independence needs to be contextualised according to the regulatory framework of South Africa (Nursing Act of 33 of 2005 and South African Guidelines for Good Clinical Practice, 2006).
- Independence for the clinical research nurse is the practical ability to provide care, exercise independent judgement, and self-governance in the scope of practice of a professional nurse.
- Choose and master difficult tasks, since such practice would enhance self-motivation, e.g. planning a dosing day or a field visit.

4.7.5 Guideline 15: Harness behaviour-focused strategies to ensure planning and organisation of research activities take place throughout the lifespan of the project

The clinical research nurse in the southern suburbs of Cape Town needs detailed project management strategies in order to successfully navigate her role and subscribe to the high standards set for her as a professional nurse.

Guideline 15 requires the clinical research nurse to consider the following actions:

- Seek out training opportunities that are focused on developing one's project management and nurse leadership skills. If these training modules are based on the latest research, they usually include behaviour-focused strategies.
- Develop planning systems around one's protocol and the associated timelines.
- In order to report adverse events timely, the clinical research nurse needs to build trusting relationships for patients to feel comfortable enough to notify the research nurse when adverse events occur.
- First interactions with other persons count. These interactions present an opportunity to hand a participant a contact card and physically check whether they enter one's number in their cell phones.
- Spend more time on a participant's first visit to discuss the contact protocols between a patient and the research team, even when one feels that one does not have the time for such a discussion.
- Make sure the participants know that they can contact you 24 hours a day. Develop an internal ethos of no bad days to ensure positive interactions with one's patients at all times.
- Keep a diary:
    - Have a plan for each day, e.g. do not leave the office unless a plan of one's activities for the next day is complied or go to work early the next morning to ensure that a plan for the day ahead is drawn up;
    - Set aside time for problem solving on a needs basis. At the start of a study, allow, for instance, two hours twice a month; and
    - Do not convene or attend unnecessary meetings.

- Develop a strategy to cope with negative interactions during a day, for example only respond to negative feedback from a monitor / sponsor / site once time has been spent to think carefully and answer appropriately. Such a strategy ensures responses that are free of emotion. A person's ability to perceive, identify, and manage emotions are important for success at work (Kumar, Adhish & Chauhan, 2014, p. 138).

4.7.6 Guideline 16: Be a transformational leader who leads through teaching

The clinical research nurse is able to nurture learning goal orientations in other people by being a transformational leader. Transformational leadership is inspiring a shared vision with role clarity, effective teamwork / organisational structures, and the provision of feedback about individual / team performance (Halm, 2010, p. 377).

Guideline 16 requires the clinical research nurse to consider the following actions that embody transformational leadership:

- Promote a learning culture by teaching new and junior nursing staff members how to develop the competencies they need to do their job professionally. It is the responsibility of nurse leaders in nursing units to establish a team culture that recognises and promotes the value of teaching and learning in practice (Henderson & Eaton, 2013, p. 197).
- Develop an authentic nature that engenders commitment of all staff members to research activities.
- Communicate a vision of the value of research in the nursing profession that would inspire junior staff members.
- Build a strong sense of identification with the project and persuade individuals to transcend their own self-interest.
- Value the transfer of new knowledge, since this culture potentially gives your team a competitive standing. When one encounters a nurse or staff member who is not conducting an activity according to the protocol use the absence of commitment as a teaching opportunity instead of reacting emotionally. Use one's own learning experiences to inspire growth and learning in other people.

4.7.7 Guideline 17: Demonstrate professionalism and excellence by using self-monitoring to sustain one's ability to be a patient advocate

Self-monitoring is the observation and control of self-presentation and expressive behaviour, as well as an awareness of environmental cues and how to act on them (Bryant, 2013). For the clinical research nurse to self-monitor during her nursing practice requires noticing cues from one's surrounding social environment and being aware of reactions to and consequences of behaviour.

Guideline 17 requires the clinical research nurse to consider the following actions:

- Be aware of the social environment that one is a member of and recognise its social cues.
- Be motivated to assist patients with receiving the best care by following the correct procedures outlined in the research process (Jones, 2000, p. 366).
- Allow your positive and competent behaviour to reflect in the social environment and use your internal motivation strategies to stay positive even in the presence of negative emotions. Research shows that positive emotional group members experience improved cooperation, decreased conflict, and increased perceived task performance (Barsade, 2002, p. 644). The patient advocacy that a clinical research nurse demonstrates is based on contextual awareness that is likely to add meaning and depth to how other people perceive the response of a clinical research nurse. In the current landscape of nursing practice, nursing codes no longer merely function as a protective shield against external influences or for individual professional to socialise. These codes are applied to accommodate the increasing ethical demands of service delivery and patient advocacy (Meulenbergs, Verpeet, Schotsmans & Gastmans, 2004, p. 336).
- Allow time to review and seek guidance from the South African Nursing Code of Conduct. Once a year, set aside time to study clinical research ethical guidance documents, e.g. the principles of ICH, GCP, SA GCP, and the Declaration of Helsinki.
- Re-evaluate your behaviour and thoughts based on these guidance documents. Ethical competence needs to consist of not only being (virtues) and doing (rules and principles) but also of knowing (critical reflection); re-evaluation is an opportunity for the clinical research nurse to critically reflect (Eriksson, Helgesson & Hoglund, 2007, p. 207).

4.7.8 Guideline 18: Be committed to life-long learning

Lifelong learning is the continual human process of learning and development (Billet, 2014, p. 19). In the profession of nursing, the clinical research nurse is an example of a self-directed learner. Studies acknowledge that nurses who self-direct their learning often go unrecognised and the resources from which they learn are not acknowledged (Jarvis, 2005, p. 657).

Guideline 18 requires the clinical research nurse to consider the following actions:

- The clinical research nurse should be aware of mistakes made and learn from them. Informal learning is a process that the clinical research nurse initiates when she recognises her mistakes.
- Aim at learning from mistakes.
- Develop experience-based learning and act on what has been learnt.
- Seek feedback from line managers and other staff members in one's learning area.
- Reflect on one's learning experience. The implementation of a reflective approach to one's learning involves challenging assumptions; such as seeking alternatives, identifying areas for improvement, and showing active and conscious engagement (Peltier, Hay & Drago, 2005, p. 253). Such reflective practice is needed when a health professional seeks to commit to lifelong learning (Cook, 2004; Mann, Gordon & MacLeod, 2009). This process allows one to address quality and productivity demands and builds an internal paradigm where work and learning become inseparable (Marsick, 1988, p. 188). A commitment to being a self-leader requires self-understanding. This quality assists the clinical research nurse with coping competently in a dynamic and complex work environment.

4.8 RECOMMENDATIONS

This phenomenological study allowed the researcher to describe the essence of self-leadership for a sample of clinical research nurses who worked in the southern suburbs of Cape Town in the Western Cape Province. Their experiences revealed that they perceived self-leadership the backbone of their nursing practice in clinical research.

The researcher recommends that these self-leadership guidelines should be included in a blended learning course for clinical research nurses in the southern suburbs of Cape Town.

This process could be facilitated by either the Global Health Network or included as a component of a local one-year postgraduate course.

4.9 LIMITATIONS OF THE STUDY

Since this study investigated a small sample in a certain context, these findings cannot be generalised beyond medical wards, psychiatric wards, day wards, and primary health care facilities located at public and private hospitals in the southern suburbs of Cape Town.

4.10 CONCLUSION

The clinical research nurse has a unique role as a professional nurse in the southern suburbs of Cape Town. Performing her role in nursing practice calls for synergy between her roles as a professional nurse and clinical researcher - developing self-leadership strategies to assist with navigating the challenges of a partially blended working environment. This study emphasises the need for self-leadership guidance in the often independent role of a clinical research nurse. The clinical research nurse is an example of a professional nurse who is called upon to assert independence as a nurse practitioner in her discipline. Clearly defined guidance on self-leadership creates room for autonomous decision making in the context of national regulations and allows for discipline appropriate skills development. The multidisciplinary health care team should be viewed as collaborative partners who strategically ensure general patient care.

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ANNEXURE A: INFORMATION SHEET

UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21 959 2274, Fax: 27 21 959 2271

Email: cordeliaep@gmail.com

INFORMATION SHEET

Project title: Guidelines for clinical research nurses about their self-leadership role in nursing practice at general nursing units in the the Western Cape.

What is this study about?

I am Cordelia Reddy, a registered Master in Nursing student at the University of the Western Cape with Prof K Jooste as my supervisor. I am inviting you to participate in this research project because you are a professional nurse who has experience in clinical research studies conducted in general nursing units in the Western Cape. The aim of this study is to explore and describe how clinical research nurses experience their self-leadership role in nursing practice in general nursing units in Western Cape.

What will I be asked to do if I agree to participate?

You will be invited to a private office in the southern suburbs of Cape Town where the researcher will conduct a one-on-one interview. This interview will take between 45 minutes and an hour. A semi-structured interview will be conducted with you. Written consent for the interview is needed. Interview The audio recording and transcript of your interview will be stored under lock and key for five years after the results of the project have been published before it is destroyed. Only my supervisor and I have access to this information.

Would my participation in this study be kept confidential?

We will do everything within our power to keep your personal information confidential. To help protect your confidentiality, one-on-one interviews will be conducted in a private office. Your interview will be recorded in such a way to ensure your anonymity. Every attempt will be made to prevent any other person from linking specific data to you. All information obtained will be stored under lock and key for five years after publication of the results. The publication of the results of the project will not mention any names or other identifiers of participants.

What are the risks of this research?

There are no known risks associated with participating in this research project.

What are the benefits of this research?

The significance of the study is that the results could be useful to generate guidelines to clinical research nurses in relation to their self-leadership role in nursing practice.

Am I obliged to take part in this research project and can I stop participating at any time?

Your participation in this research project is completely free and voluntary. You may choose not to take part at all. If you decide to participate in this research, you may withdraw at any time during the study. If you decide to withdraw from the study, you will not be penalised in any way, neither will you forfeit any benefits to which you otherwise qualify.

How do I get my questions answered?

This research is being conducted by Cordelia Reddy, registered at the University of the Western Cape. If you have any questions about the research study, please contact:

Cordelia Reddy

2 Du Barry

171 Beach Road

Mouille Point

8001

Cape Town

Cell Phone: 083 305 2627

Email: cordeliaep@gmail.com

Should you have any questions with regard to this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Head of Department

Prof Yinka Adejumo

Tel: 021 959 3024

Email: oadejumo@uwc.ac.za

Dean of the Faculty of Community and Health Sciences

Prof Hester Klopper 021 959 2631

Email: hklopper@uwc.ac.za

Dean of the Faculty of Community and Health Sciences

University of the Western Cape

Private Bag X17

Bellville 7535

This research has been approved by the Senate Research Committee and Ethics Committee of the University of the Western Cape.

ANNEXURE B: WRITTEN INFORMED CONSENT SEMI-STRUCTURED INTERVIEW

UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21 959 2274, Fax: 27 21 959 2271

E-mail: cordeliaep@gmail.com

INFORMED CONSENT FORM

Title of the research project: Guidelines for clinical research nurses about their self-leadership role in nursing practice in general nursing units of the Western Cape.

The study has been described to me in a language that I understand. I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name ……..

Participant's signature ……

Witness ……

Date …….

Should you have any questions with regard to this study or wish to report any problems you have experienced related to the study, please contact the study coordinator:

Name of the study coordinator': Prof Karien Jooste

University of the Western Cape

Private Bag X17, Bellville 7535

Telephone: (021) 959 2274

Cell: 082 897 2228

Fax: (021) 959 2271

Email: kjooste@uwc.ac.za

ANNEXURE C: PERMISSION LETTER TO CLINICAL RESEARCH ORGANISATION

UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21 959 2274, Fax: 27 21 959 2271

E-mail: cordeliaep@gmail.com

Dr H. C. Botha

3 Degree Clinical Research & Consulting

Office No. 06

Howard Centre

Pinelands

7450

REQUESTING PERMISSION TO CONDUCT A RESEARCH STUDY IN THE OFFICES OF 3 DEGREE CLINICAL RESEARCH & CONSULTING

I hereby request to conduct a research study in the offices of 3 Degree Clinical Research & Consulting. The study is entitled: Guidelines for clinical research nurses about their self-leadership role in nursing practice in general nursing units of the Western Cape. This study is part of the requirements for acquiring a Master's degree in Nursing and will be done under

the supervision and guidance of Prof K. Jooste at the School of Nursing, University of the Western Cape.

Data will be collected by conducting semi-structured interviews. These semi-structured interviews will be conducted with professional nurses who have been involved in clinical research in general nursing units in the southern suburbs of Cape Town in the Western Cape Province. Participants will be required to meet the researcher on a designated day at the 3 Degree offices for a semi-structured interview. The researcher will adhere to the rights of participants to privacy and confidentiality. The identity of all participants will be protected. The audio recordings and transcripts of the interviews will only be identified by their allocated code numbers. The name of the institutions at which these professional nurses have been involved in clinical studies will not appear in the research report. All records will be kept for 5 years after publication of the results and then it will be destroyed. Only the supervisor and the researcher will have access to the data. The participants will not be coerced into participation and should they wish to withdraw at any time during the study, their wish will be respected. The researcher will ensure adherence to the highest standards of research planning, implementation, and reporting.

If you have any questions about the research study, please contact:

Cordelia Reddy

2 Du Barry

171 Beach Road

Mouille Point

Cape Town

8001

Cell Phone: 083 305 2627

Email: cordeliaep@gmail.com

Should you have any questions with regard to this study or if you wish to report any problems you have experienced related to the study, please contact:

Head of Department

Prof Yinka Adejumo

Tel: 021 959 3024

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Dean of the Faculty of Community and Health Sciences

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Head of Department

Dean of the Faculty of Community and Health Sciences

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This research has been approved by the Senate Research Committee and Ethics Committee of the University of the Western Cape.

ANNEXURE D: INTERVIEW SCHEDULE

Tell me about your experiences as an independent clinical research nurse who visits nursing units?

How do you direct yourself to complete your tasks independently in practice?

Examples of probing questions and statements:

- What do you mean?
- Tell me more…

ANNEXURE E: BRACKETING

The process of bracketing was a very personal one for the researcher, due to the novel nature of her topic. Engaging with the literature, the research participants and a not for profit international organisation who supports clinical research personnel both locally and internationally know as the Global Health Trials Initiative, opened the researcher up to the possiblities of the research topic and moved her away from her presuppositons. From the 9 months preparation time, taken to review the literature and describe a topic which would best fit the research context and the researchers aims. From the onset the researcher found that it was vital not to allow her personal experiences of alienation and aloneness to influence her analysis of how other clinical research nurses had experienced their jobs. The questions posed to interviewees were sometimes seen as probes which where leading – based on the researchers experience.