INFORMED CONSENT: COMMUNICATION AND MISCOMMUNICATION IN CLINICAL TRIALS

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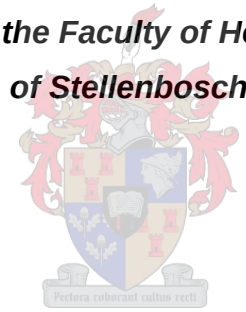
Thesis presented in partial fulfilment of the requirements for the degree of Masters of Nursing Science in the Faculty of Health Sciences at the University of Stellenbosch



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DECLARATION

By submitting this assignment electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the copyright thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

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ABSTRACT

Background

Informed Consent (IC) has been proposed as the optimal method for ensuring the ethical entry of patients into clinical trials. IC is a vital part of the research process and as such entails more than obtaining a signature on a form. The IC must be given freely, without coercion, and must be based on a clear understanding of what participation involves.

Aim

The overall aim of this study was to attain an understanding of participants' knowledge regarding informed consent when participating in a research project.

Methods

The study was conducted at two public hospitals in a city in the Eastern Cape Province of South Africa. The quantitative study used descriptive survey design. A self administered questionnaire was used as a tool for data collection.

Results

The sample size consisted of 170 women with an average of 25.9 years. The majority had completed secondary level education. More than half of the participants did not have knowledge of the purpose of the original study. The majority of participants did not have knowledge of their responsibilities. Forty-two percent gave uninformative responses and 26% indicated they did not know their responsibilities. None of the participants understood the concept of randomization. The majority (85.9%) of participants indicated that information provided on the IC forms was sufficient for them to decide to participate.

Conclusion

Despite extensive efforts to ensure that participants understood their participation in the original studies, this study found poor recall of vital information for IC. A signed informed consent does not guarantee that participants understand information given.

Recommendations

The existing methods of communicating and obtaining of an informed consent seem to be insufficient for participants to make an informed decision. A new approach with more interactive features such as combination of audio-visual techniques might increase the possibilities of the understanding.

OPSOMMING

Agtergrond

Ingeligte toestemming (IT) is voorgestel as die optimale metode om die etiese toelating van die pasiënte vir kliniese toetse te verseker. IT is 'n belangrike deel van die navorsingsproses en as sodanig behels dit meer as die verkryging van 'n handtekening op 'n vorm. Die IT moet vrylik gegee word, sonder dwang en moet gebaseer wees op 'n duidelike begrip van wat die deelname behels.

Doel

Die algemene doel van hierdie studie is om 'n begrip van die deelnemers se kennis met betrekking tot ingeligte toestemming te bepaal, wanneer hulle deelneem aan 'n navorsingsprojek.

Metodes

Die studie is uitgevoer by twee openbare hospitale in ’n stad in die Oos-Kaap in Suid-Afrika. Die navorsingsontwerp is beskrywend van aard en ’n kwantitatiewe benadering is toegepas. ‘n Self-geadministreerde vraelys is as 'n instrument gebruik om data in te samel.

Resultate

Die steekproefgrootte het bestaan uit 170 vroue met 'n gemiddelde ouderdom van 25.9 jaar. Die meerderheid van die vroue het opleiding tot op sekondêre vlak. Meer as die helfte van die deelnemers het geen kennis van die doel van die oorspronklike studie gehad nie. Die meerderheid van die deelnemers het ook nie kennis van hul verantwoordelikhede gehad nie. Twee-en-veertig persent het nie toepaslike antwoorde gegee nie en 26% het aangedui dat hulle nie weet wat hul verantwoordelikhede in die studie is nie. Nie een van die deelnemers het die konsep van verewekansiging verstaan nie. Die meerderheid (85.9%) van die deelnemers het aangedui dat die inligting wat deur die IT verskaf word voldoende was om te besluit of hulle aan die studie wou deelneem.

Gevolgtrekking

Ten spyte van uitgebreide pogings om te verseker dat deelnemers hulle deelname verstaan het in die oorspronklike toetsing, het hierdie studie die swak herroeping van belangrike inligting aangaande IT bewys. ‘n Ondertekende ingeligte toestemming gee geen waarborg dat die deelnemers die inligting waarvoor toestemming geteken is, verstaan nie.

Aanbevelings

Die bestaande metodes van die kommunikasie en verkryging van ingeligte toestemming blyk onvoldoende te wees om deelnemers ingeligte besluite te laat neem. ‘n Nuwe benadering met meer interaktiewe eienskappe soos ’n kombinasie van oudio-visuele tegnieke mag die moontlikhede om te verstaan, meer duidelik maak.

Key Words

Bias, clinical trial, communication, ethics, exclusion, inclusion, informed consent (IC), miscommunication, participant, understanding.

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Table of content **Page**

List of tables

List of figures

List of Annexures

List of Abbreviations and Acronyms

DoH	Declaration of Helsinki
EU	European Union
GCP	Good Clinical Practice
IC	Informed Consent
IRB	Institutional Review Board
NUFU	Norwegian Programme for development, Research and High Education
PI	Principal Investigator
SES	Socio Economic Status
TRA	Theory of Reasoned Action
TM	Therapeutic misconception
USA	United States of America
WHO	World Health Organisation
HREC	Human Research Ethics Committee

CHAPTER 1
INTRODUCTION TO STUDY

1.1 Introduction

Informed consent (IC) refers to an agreement between the researcher and the study participant (or his or her legally authorised spokesperson) to provide the participant with full knowledge of all the possible risks and benefits involved in a clinical trial. This agreement contains information of relevant facts related to the purpose, setting and rationale of the trial. A researcher may be held responsible for an injury caused by an undisclosed risk while the participant is in the study.

IC can be defined as a process of information exchange that by its very nature requires a dialogue between a patient and provider (Schenker, Wang, Selig, Rita & Fernandez, 2007:294). However Neff (2008:1338) states that consent is much more than just the form, regardless of time spent developing and modifying it. In reality consent is about a process that includes a non-coercive communication between subject and investigator. Additionally obtaining informed consent implies giving information to potential participants regarding the nature of the research procedure, scientific purpose and alternatives to study participation (South Africa Department of Health, 2006).

According to Vanderpool (2009:258) a fully informed consent results from a process of communication between researchers and potential subjects;

1. that conveys sufficient, relevant, and required information about the research in question,
2. that is comprehended by the subjects,
3. who voluntarily or freely choose to enroll in the research.

Chapter one provides the reader with a general overview of the research study, which entails the investigation of the understanding of IC from participants who participate in clinical trials.

1.2 Aim of the study

The overall aim of this study was to attain an understanding of participants' knowledge regarding informed consent when participating in a research project.

1.3 Objectives

The objective of the study was to assess how well participants understood why they agreed to participate in a research project in relation to the:

- purpose of the study
- treatment procedures
- schedule and duration of the study
- confidentiality
- potential risks
- side effects or benefits
- participant’s rights to withdraw
- contact information and role in the trial
- costs or incentives
- Reason/s for participation.

1.4 Significance of the study

There is currently no study that assessed communication and miscommunication of informed consent in South Africa. The findings of this study may identify gaps that exist during communication of IC in research studies. Furthermore the results of this study may help future researchers to explore more interactive features that can be incorporated when obtaining informed consent.

1.5 Rationale

The researcher is of the view that the participants do not always understand the full content of an IC. It is not always that participants understand and know what they are signing for when they enrol in research studies. Furthermore the researcher believes that participants confuse research with treatment. According to Lidz (2006:535) therapeutic misconception means individuals may confuse the goals of the research with those of treatment and may make decisions that do not rest on adequate understanding.

The researcher also believes vulnerability of persons and populations also do affect the communication of IC. Participant's vulnerability and their motivations for participation should be considered, so as to get sense of confidence that when they consent to participate in studies, they are truly informed. According to Mkandawire-Valhmu, Rice and Bathum (2009:1732), it is important for researchers to understand, through research, the needs of the most vulnerable in our communities while at the same time maintaining their human rights and dignity. There is therefore a need for further investigation into the understanding of research among vulnerable populations.

It has been documented that obtaining consent from certain female populations is a further challenge as women in poorer countries often lack formal education and may not understand the uncertainty or the risk that exists within some of the clinical trials (Mills, Nixon, Singh, Doima, Nayyar, & Kapoor, 2006:308).

1.6 Background literature

IC has been proposed as the optimal method for ensuring the ethical entry of patients into clinical trials therefore investigators have to obtain IC before enrolling participants in clinical trials (Joffe, Cook, Cleary, Clark & Weeks; 2001:1772). The current system of human-subject-research oversight and protections has developed over the last five decades and the principles of conducting human research were first developed as the Nuremberg code to try to stop Nazi war criminals (Rice, 2008:1325).

The Nuremberg Code has generally been seen as arising from the Nuremberg Medical Trial and Informed consent has been an axiom of post–World War II clinical research and practice. (Weindling, 2001:37). IC is the first principle of the 10 principles of Nuremburg code of 1947 (Lindegger & Richter, 2000:313). These authors posit that the aim of the code was to regulate clinical trials so as to prevent abuse of human subjects as that was practiced by the Nazi physicists during World War II. It is generally accepted that IC, as required in human research, incorporates four views;

- disclosure of all relevant information about the research
- comprehension by the prospective participant of this information to make an informed decision
- freedom from all coercion of the prospective participant
- explicit and formal consent by the participant, usually in written form (Lindegger & Richter, 2000:313).

Obtaining informed consent can lead to misconceptions by participants. For instance participants may consent to be involved in clinical trials as they may then feel that they are eligible to free medical services offered during their participation in the trials. This is particularly evident in populations of low income status (Rothmier, Lasley & Shapiro, 2003:1040). In these populations of low income status, the severity of disease or unstable emotional status may also contribute to the lack of proper understanding of what is expected of them.

The principle of IC is that consent is freely given without coercion from researchers or local community. Therefore all trial related information should be presented in the local language, and should address varying levels of education, both written and oral presentation (Mills Nixon, Singh, Dolma, Nayyar & Kapoor, 2006:309).

According to the South African Good Clinical Practice guideline (GCP), the participants should be informed that the trial involves research. In addition the purpose of the studies and interventions must be communicated. Furthermore the participants should be informed of the possibility of random assignment to intervention or control group. The researchers should clarify that neither the participant nor the researcher would know whether he/she will be allocated to intervention or control group. The participants will fall in either of the groups by chance, the possibility of invasive procedures, what the subject's responsibilities are in the trial and aspects of the trial are experimental should be communicated (South Africa Department of Health, 2006).

The Nuremberg code was developed in 1947 and at that time there were no laws, regulations, codes, or formal documents that stated ethical standards for human-subjects research. The trial proceedings resulted in the development of a document, named the Nuremberg Code. This document articulated the basic requirements for

conducting research in a manner that respects the fundamental rights of human subjects (Rice, 2008:1326).

According to Carlson, Boyd and Webb (2004:708), there are 10 principles that were laid down to which must be followed by physicians when carrying out experiments on human subject and are as follows;

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent. The participants should be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit or duress. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment. It must. The participant must be informed of the method and means by which the study is to be conducted, all inconveniences, hazards to be expected; and the possible effects upon his/her health from participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and acknowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

1.7 Research question and statement

How well do participants understand informed consent? It is the researcher's view that research participants may not always understand the full content of an informed consent.

1.8 Research methods

The research design will be covered in depth in chapter three. This study used a descriptive design to explore how well participants understood informed consent when participating in a study. A questionnaire was formulated based on the IC template of the World Health Organization. The questionnaire consisted of 33 questions.

1.9 Study population and sampling

The study was carried out in a city in the Eastern Cape Province. Participants were recruited from existing studies conducted at a research unit.

There were three studies taking place at the time of this survey. The primary objectives of study B was to determine the demographic, socioeconomic factors, infant feeding practices, immunisation, and micronutrient status on infant growth, diarrhoea and respiratory diseases in infants of age six weeks to nine months. Study A was a randomized controlled trial comparing efficacy, safety and acceptance of the intra uterine contraceptive device and injectable depot progestogen in reducing pregnancy rate. The primary objective of study C was to assess whether massaging the uterus for 30 minutes may be as effective, or more effective as oxytocin injection to prevent post-partum haemorrhage.

Only those who were able to converse (read or write or speak) in either Xhosa or English were recruited. Participants were selected using convenience sampling. Newly recruited participants who agreed to participate in the research unit studies were approached to participate in the IC study. Informed consent was obtained from the participants, 8 to 48 hours after being successfully enrolled and signing informed consent to any of the research unit studies. It was estimated that 50 women would be enrolled onto trials every month. The statiscian advised on the sample size of 170 participants. It was calculated using power of 80% and p-value of 0.05.

1.10 Data Analysis

Quantitative data was entered onto a Microsoft excel sheet and analysed. Findings are presented in tables and texts, interpreted and discussed. The statistic test used was Chi-square. The common themes and written descriptions of findings were formulated from responses of open-ended questions. The qualitative analysis of the open ended

questions was done on all 170 questionnaires although it was expected that saturation of new themes would be reached after the first 50 questionnaires.

1.11 Inclusion criteria

All the participants that were at the time of the study, participating in any of the research unit studies and consented to participate in the IC study were included. The participants had to be able to converse (read or write or speak) in either English or Xhosa.

1.12 Reliability and Validity

The pilot study was done to test the questionnaire for reliability and validity. According to Burns and Grove (2007:552), reliability refers to the consistency with which an instrument measures what it is supposed to measure, while validity is the extent to which an instrument measures what it is supposed to measure. Reliability testing was done to measure the amount of random error in the instrument; the data collectors were taught about the study and the procedures of how the study should be carried out.

Validity is a reflection of the relationship between a concept being measured and the measurement itself (Burns & Grove, 2005:378). Internal validity/truth-value was insured by being satisfied that the participants accurately understood the questions and agreed with the way it was interpreted. The researcher clarified the information given to her with the participant to ensure that it was correctly understood.

The questionnaire was given to five experts to confirm, face, content and criterion validity. A pilot study was conducted to test the questionnaire for reliability and validity.

1.13 Ethical consideration

A signed informed consent was obtained from the participants. The proposal and informed consent to conduct this study was approved by Human Research Ethics Committee of University of Stellenbosch. The research staff consisted of individuals who had completed a course in Good Clinical Practice within the past two years, assuring that the research would be done according to the ICH GCP guidelines. The study was one of the larger studies taking place in the research unit. Permission to carry out the study was sought at the institution and granted.

1.14 Dissemination of results

The report of this study will be submitted to Stellenbosch University as a fulfillment for the master's degree in nursing and an electronic copy made available on internet via the university's SUNscholar portal. Papers will be presented at local and international conferences and a manuscript submitted to a peer reviewed accredited journal for publication.

1.15 Budget

The researcher's study fees as well as any project related financial needs were funded by Family. Initially the funding for transport to research site, school fees and paper

needed for printing as well as payment of the statistician was funded by NUFU and PROMISE PEP.

1.16 Definitions

Bias

Bias is an influence that produces a distortion in the study results (Polit & Beck, 2006:42).

Clinical trial

A clinical trial is a study designed to assess the safety and effectiveness of a new clinical treatment which sometimes may involve a number of phases, of which one (phase 2) is a randomised clinical trial using an experimental design (Polit & Beck, 2006:496).

Communication

Communication is the process of sending and receiving messages between human beings and it includes both content and instruction proportions and feedback loops and can be digital and analogic (Friedman, Bowden & Jones, 2003:649)

Ethics

Ethics are systems of moral values that is concerned with the degree to which research actions adhere to professional, legal, and social obligations to the study participants

(Polit & Beck, 2006:499). Additionally ethics are referred to as the discipline that deals with principles of moral values and moral conduct (LoBiondo-Wood & Haber, 2010:577).

Exclusion

Exclusion is a criteria that specify characteristics that a population does not have (Polit & Beck, 2006:499). It is the process of selecting those who are not legible to take part in the study or can be referred to as process of excluding or being excluded in a study.

Inclusion

Inclusion a sampling criteria with characteristics that the subject or element must possess to be part of the target population (Burns & Groove, 2007:325). It is the Process of selecting those who are legible to take part in the study or can be referred to as a process of being included in the study.

Informed consent (IC)

An informed consent is an ethical principle that requires a researcher to obtain the voluntary participation of subjects after informing them of potential benefits and risks (Lobiondo-Wood & Haber, 2010:597). In addition, Burns and Groove (2009:704), defines IC as a prospective subject's agreement to voluntary participate in a study, which is reached after the subject assimilates essential information about the study.

Miscommunication

Miscommunication in research ethics is communication failure between the staff designated with the responsibility of providing IC and the participant. This can occur

when insufficient information is provided or participant misunderstanding information provided.

Participant

Participant is an individual who participates and provide information in a study (Polit & Beck 2006:511). Furthermore this individual provides the researcher with information relevant to the study or consents to be observed during the course of the research

Understanding

Understanding is when the participant can comprehend information provided by the researcher.

1.17 Summary

The purpose of chapter one was to acquaint the reader with a short overview of what could be expected of this research project. This study is conducted to evaluate the understanding of informed consent when participants consent to partake in a clinical trial or any research study.

Chapter one outlined the introduction of the project. The next chapter provides a layout of literature on important aspects of informed consent. The third chapter is a description of the methodology of the study as well as the instrumentation. In chapter four, the results of both the qualitative and quantitative data are presented. Chapter five contains a discussion of the results and recommendations are given.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

A review of literature on informed consent (IC) was done to gain a background and a more in-depth understanding of all issues that may impact research participant's understanding of IC. Literature was searched in medical journals, PubMed, the National Library and various other resources available.

This chapter covers an overview of the historic background of the origin of informed consent. It covers the theoretical framework of informed consent that guides this study. Language barriers and issues related to the understanding of IC as well as the misconceptions that exist between treatment and medical research are also discussed. The gaps in the literature of informed consent have also been identified.

2.2 Theoretical frame work

2.2.1 Theory

Theory is a creative and rigorous structuring of ideas that project a tentative, determined, and systematic view of phenomena (George, 2002:5). According to LoBiondo-Wood and Haber (2010:58), it is a set of interrelated concepts, definitions and

propositions that present a systematic view of phenomena for the purpose of explaining and making predictions about those phenomena. It is further viewed to suggest a direction on how to view facts and events and theories cannot be equated with scientific laws, which predict the results of given experiments hundred percent of time (George, 2002:5). Pilot and Beck (2006:511) refer to it as an abstract generalisation that presents a systematic explanation about the relationships among phenomena.

2.2.2 Framework

A framework is an abstract, logical structure of meaning, such as a portion of a theory, which guides the development of a study. It is tested in the study and enables the researcher to link the findings to the body of knowledge used in nursing (Burns & Groove, 2007:540).

A conceptual framework or theoretical framework of a research report is a structure of concepts and theories pulled collectively as a map for the study (LoBiondo-Wood & Haber, 2010:57). The rationale for the map of the study provides rationale for the development of research questions or hypotheses (LoBiondo-Wood & Haber, 2010:57).

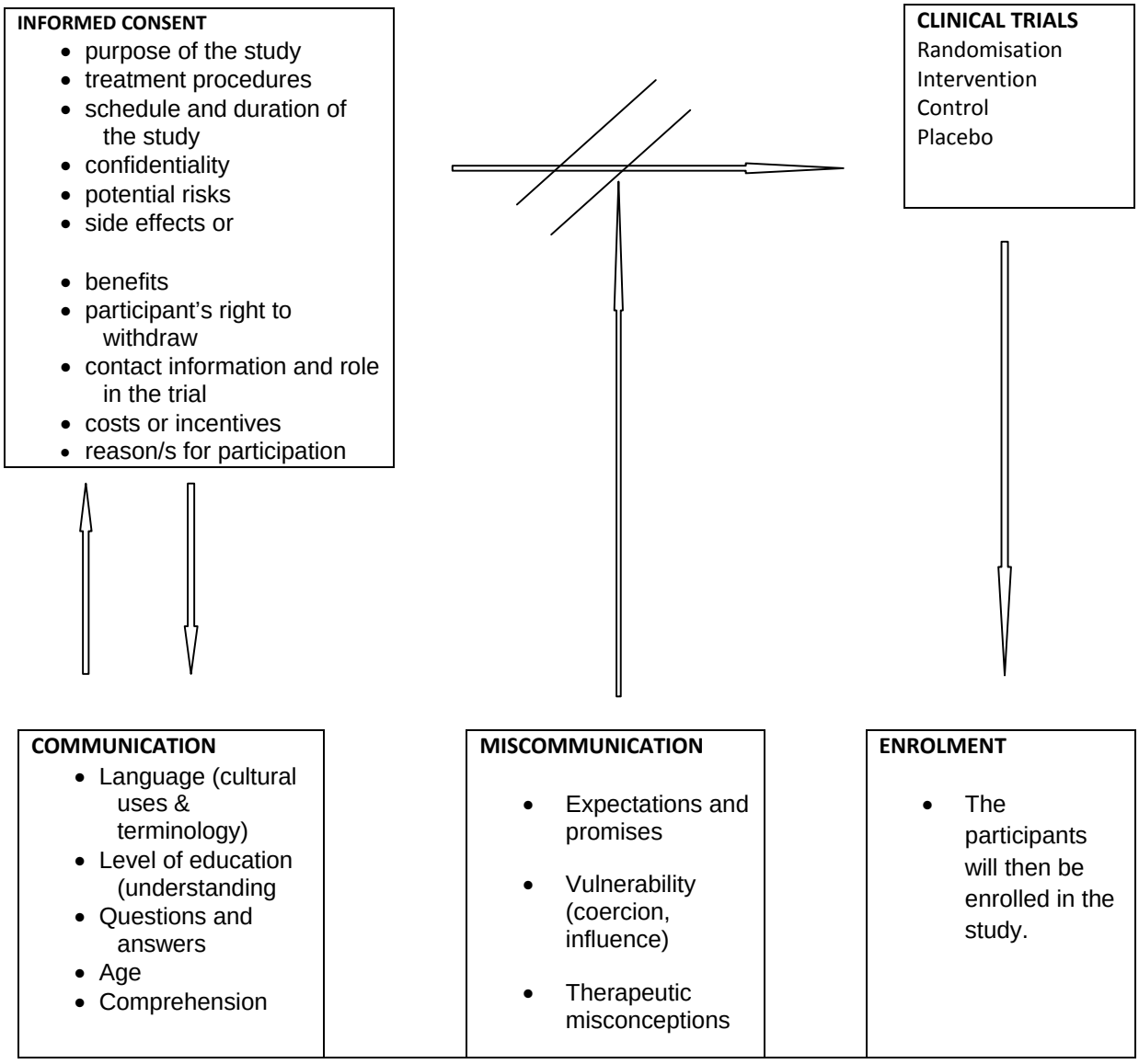

Figure 2.1 conceptual map for Informed Consent Study

(Developed by researcher from experience G.P.Moloi)

As illustrated in figure 2.1, IC is detailed with information of purpose of the study, treatment procedures, schedule and duration of the study, confidentiality, potential risks, side effects or benefits and participant' right to withdraw. Others include, contact information and role in the trial as well as costs or incentives available and reason for participation (Department of health, 2006). The communication process takes place before enrolment in clinical trials. Communication brings about issues of language differences, cultural uses and terminology. Issues relating to the level of education and understanding of information are evident during communication.

There is a possibility of miscommunication before enrolment in clinical trials. Researchers can make promises that result in participants having higher expectations. The promises may indirectly result in coercion of the participants to enrol in the studies or therapeutic misconception by the participants. Vulnerability of the participants may influence the extent of miscommunication and confusion of research versus treatment. The communication of research aspects such as randomisation, control, intervention and placebo takes place in clinical trials before enrolment of participants.

2.2.3 Egoism

The researcher believes that before you can think of somebody else's interest you should think of yourself. Before someone puts oneself in any commitment he/she must judges if it will be of benefit or compromise his/her life. Egoism focuses on self-interest. This ethical principle is used as justification when something is done to further an individual's own welfare. Asking the following question can best sum up the principle: *Does the action benefit me, as an individual, in any way?* According to Pera and Van Tonder (2005:29) for the egoist, the morally right thing to do is whatever promotes self-interest. An IC is meant for an individual to read and understand or to comprehend information provided and decides if it benefits his/her or if necessary for oneself to

participate in particular research studies. The signing should be done after judging if the consent will benefit or compromise his/her life.

2.2.4 Theory of Reasoned Action

According to Webber, Martin and Corrigan (2007:2438), the Theory of Reasoned Action (TRA) includes behaviours that people perform because they choose to do so. The TRA eludes an individual's intention to perform a given behaviour as the single best predictor of that person's behaviour. The TRA would predict that if someone believes that people who are important to them would support the signing of consent, then they would be more likely to do so (Weber et al, 2007:2438).

2.2.5 Utilitarianism

According to Pera and Van Tonder (2005:30) utilitarianism assumes that one can weigh and measure harms and benefits and produce greatest possible balance of good over evil for most people. According to Nord (2006: 67) utilitarianism permits the causing of harm to an innocent victim when doing so would likely cause benefit to others greater than the harm to the victim. Common morality, by contrast, does not accept this precept.

2.2.6 Developed theoretical frame work for IC study

The researcher acknowledges that all individuals need to have full control of their lives and freedom to decide what is right and wrong for them to accomplish full control of one-self.

It has been documented by Pera and van Tonder (2005:152) individuals have the right to conduct their lives as autonomous agents without external control, coercion or exploitation, especially when they are asked to participate in research. This basically refers to self- determination by an individual of what is right and wrong for them. It is therefore the researcher's responsibility to respect the autonomy of vulnerable individuals. An individual must refrain from actions which may cause harm but do good over evil.

2.3 History of informed consent

It is documented that before World War II, the evidence-based medicine era, clinical research was an informal part of medical practice. According to Rice (2008:1326), in the last half century, the level of oversight on human subjects has exploded from almost none to what is now an exhaustive system of protections. Participants of such studies were frequently unaware that the treatments suggested by their physician were in essence experimental.

The United States of America is named as the country of origin of the informed consent. The initial aim was to make sure that the correct dignity of the patient's independence

and choice of medical options were reserved at the time of decision making (Mallardi, 2005:313).

2.3.1 Tuskegee experiment

Early in the 1930's, about 400 black men with syphilis were recruited in a study in Tuskegee, Alabama in order to investigate the natural progression of untreated syphilis (Cohen, 2008:704). The men were informed that they had "bad blood values" and that they would get free treatment if they decided to join the study. At the time of the study there was no cure for syphilis, but in the 1940's, with the introduction of penicillin as a cure of syphilis, the study participants were still denied treatment (Sharma 2009:256). Many of the participants were illiterate, which made it difficult for them to understand what they were going through. The Tuskegee study was an important reason for the development of the Belmont Report (Cohen, 2010:704). Subjects were denied the opportunity of informed consent and were coerced to join the study. If they were properly informed they would have made an educated decision. Another disadvantage was that they were vulnerable due to being desperate for treatment. Participants were promised that being involved in the study they would get free treatment.

2.3.2 Nazi experiments

The Nazi experiments were carried out in Germany. The Jewish prisoners were tortured and usually to death. There were more racial experiments carried out at the time of the Nazi experiments. Some 300 prisoners were immersed in ice-cold water, or strapped naked to a stretcher in the Polish winter, while rectal temperature, heart rate, level of consciousness and shivering was carefully monitored and charted (Bogod,

2004:1155). Most participants were allowed to freeze to death; in some resuscitation was attempted by various methods, with active reheating in a warm bath proving the most effective (Bogod, 2004:1155).

According to the Good Clinical Practice Guideline (Department of Health, 2006) it is a person's right to refuse or participate in research and that shows respect for human dignity. The main ideal goal for process of informed consent is to make sure that the research participants make informed decisions prior to participating and then implement them.

2.3.3 Nuremberg code

A trial was done in Nuremberg, on December 19, 1946, of Nazi doctors and a code was defined in which the judges, all Americans, clearly emphasized a view of medical research and technology. Science should never transform or consider human beings as an instrument to be employed for scientific purposes (Mallardi, 2005:313).

At the time when the Nuremberg code was developed in 1947, there were no laws, regulations, codes, or formal documents that stated ethical standards for human-subjects research (Rice, 2008:1326). The trial proceedings resulted in the development of this document called the Nuremberg Code that articulated the basic requirements for conducting research in a manner that respects the fundamental rights of human subjects (Rice, 2008:1326).

This code has generally been seen as arising from the Nuremberg medical trial and Informed consent has been a saying of post–World War II clinical research and practice (Weindling, 2001:37). IC is the first of the 10 principles in the Nuremburg code of 1947 (Lindegger & Richter, 2000:313). These authors state that the aim of the code is to regulate clinical trials so as to prevent abuse of human subjects as practiced by the Nazi physicists during World War II. It is generally accepted that IC, as required in human research, incorporates four views;

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- comprehension by the prospective participant of this information to make an informed decision
- freedom from all coercion of the prospective participant
- explicit and formal consent by the participant, usually in written form (Lindegger & Richter, 2000:313).

The ten principles can be summarized in three basic principles. These are;

- the researchers' responsibility towards the research subject shall always be greater than that towards the society,
- the ethical aspects between therapeutic and non-therapeutical trials differ from each other,
- the concept of giving informed consent is essential.

The full list of the 10 codes is listed in Chapter One (page 5).

It can be concluded that the Nuremberg Code arose from the concerns of allied medical war crimes investigators as they encountered the survivors of the human experiments and gathered the records of medical atrocities in concentration camps and clinics (Weindling, 2001:70).

2.3.4 1964-The declaration of Helsinki

The Declaration of Helsinki (DoH) was first adopted in 1964 and it has risen to a position of prominence as a guiding statement of ethical principles for doctors involved in medical research (Carlson, Boyd & Webb 2004:696). The DoH was developed by World Medical Association and is a further development of the ethical principles of the Nuremberg code (Striefel, 2001:41).

2.3.5 1979-Belmont Report

The Belmont Report is an approximately 5,500-word document that describes three fundamental principles that are now accepted as the minimum requirements for ethical human-subjects research (Rice, 2008:1328). In April of 1979, Belmont Report was issued, which established the ethical principle for the treatment of research subjects in the United States. The three ethical principles to guide the conduct of research involving human subjects that are;

- respect for persons,
- beneficence and
- justice (Byerly, 2009:177).

The above principles are generally accepted and are particularly relevant to the ethics of research involving human subjects.

Respect also called the autonomy principle, has also been addressed in the Nuremberg code and points out that informed consent should, if possible, be made prior to research.

Justice states that individuals should be selected justly. In other words vulnerable participants should not take part in studies unless there are strong motivations for these individuals to partake.

Beneficence means that benefit profile must be analysed and that the benefits must clearly outweigh the risks in order to proceed with the research (Byerly, 2009:177).

2.3.6 1974-The National Research Act

According to Byerly (2009:176), the revelation of the Tuskegee Syphilis Study led to the National Research Act of 1974 in the United State of America. The National Research Act led to the establishment of modern Institutional Review Board (IRB) system and ethical standards for human research subjects (Rice, 2008:1328). The legislation created the National Commission for Protection of Human subjects of Biomedical and Behavioral research.

2.3.7 The Institutional Review Board

Byerly (2009:176), states that the Nuremberg Doctor's Trial that occurred at the end of World War II is commonly cited as the experience that drew attention to the need for a formal system for the protection of individuals who participate in research studies. The

United States of America (USA), National Research Act paved a way for the modern IRB system of regulating human-subjects (Rice, 2008:1328). IRB review is integral to ensuring regulatory compliance and ethical conduct of research involving human subjects (Byerly, 2009:182). Over the years, much has been done to secure protection for participants in clinical research. No research on humans will be done without considering how best to protect the interests of the research subject.

2.3.8 GCP guideline

The GCP guideline is an integrated scientific quality standard for designing, recording and reporting trials involving participation of human subjects (South Africa Department of Health, 2006). The GCP guidelines contain information on what informed consent should contain in order to give the potential participant the opportunity of making an educated informed decision. The agreement also contains the procedures regarding the handling of the informed consent form between the researcher, institutions and participant. The concepts are as explained below (South Africa Department of Health, 2006).

2.4 Principles of informed consent for trial participants

According to GCP guidelines, in conduct of Clinical Trials with human participants, there should be an adequate information package available for use in the process of seeking IC for participants of the study. It should include contact details for the Medical Control Council and the relevant research ethics committee. It is further stipulated in the guidelines that both the IC discussion and the written IC form and any other written information to be provided to participants should include explanations of the following;

The participant must be aware prior to participation that the study is done to find out answers for the researcher and not treatment (South Africa Department of Health, 2006). According to Lidz (2006:535) individuals may confuse the goals of research with those of treatment and may make decisions that do not rest on adequate understanding. This is referred to as therapeutic misconception.

It is further stipulated in the GCP guidelines that, it is vital for participants to be aware of the purpose of the trial. The information regarding trial treatment should be clearly explained and possibility of random assignment to each in cases of randomised trials. The participants must be aware of the procedures to follow responsibilities before joining. Participation should be voluntary and participants should be informed that they have right to refuse and that will not affect their routine care. The participant should be made aware of the expected duration of participation, benefits and risks. The compensation and treatment available in the event of trial related injury and requirement to preserve confidentiality must be clarified. The contact name, number of the Principal Investigator (PI) and directly responsible investigator and identity of a sponsor should be provided (South Africa Department of Health, 2006).

2.5 Communication

Communication is essential to everyday life and is the centre of professional practice. The way in which people communicate is unique and influences the quality of the relationships with those they interact with (Jootun & McGhee, 2011:40). Furthermore Jootun and McGhee (2011:41), illustrate that this process requires a vast range of skills in intrapersonal and interpersonal processing, listening, observing, speaking, questioning, analysing and evaluating.

Good communication is the foundation of safe, effective patient and family-centered care, whereas poor communication is often cited as the thrust for malpractice suits, non-adherence to treatment regimens, and patient dissatisfaction (Knops & Lamba, 2010:825). Furthermore these authors suggest that failure to align communication

styles and goals can lead to miscommunication and frustration. Additionally Williams, Hanson, Boyd, Green, Goldmon, Wright and Corbie-Smith (2008:1221) refer to effective communication as fundamental for mutual understanding, informed decision making, and effective delivery of health care.

In a qualitative study carried out to find out barriers to effective communication across the primary and secondary interface, communication issues across each of the stages of the patient journey included content, tone, style, and format (Farquhar, Barclay, Earl, Grande, Emery & Crawford, 2005:363). However most often it was the speed at which information was received that caused difficulties (Farquhar et al, 2005:3630). According to Le-Roux (2002:41) language and culture are inextricably bound and cross-cultural communication is complex. Furthermore speaking the same language does not guarantee effective intercultural communication.

Figure 2.2 The process of communication (Adapted from Jootun & McGhee, 2011:42)

The process of communication starts with the information or message that needs to be conveyed to another person who is referred to as receiver and the one who conveys the message is the sender (see figure 2.2). The message is encoded to eliminate elements of confusing the receiver and thus communication takes place. The message is then

decoded so that it can be well understood by the receiver and then message will be received (Mc Ghee, 2011:42). The receiver of the message then sends feedback after receiving and understanding the message. The process then starts all over again (Mc Ghee, 2011:42). According to Bahri (2010:1067) communication may be defined as a two-way process that involves a sender transmitting information to a receiver with a declared intention or expectation.

There are different channels of communication that can be used. The message can be sent through face to face conversation. That is when the sender and the receiver are at each other's vicinity. Communication can also take place by telephones or through video conferencing or writing of letters. Electronic mails can also be used or faxing of messages or desired information that needs to be sent.

2.6 Comprehension

Comprehension is the first step in the critical appraisal process and involves understanding of terms and concepts in a report as well as identifying study elements and grasping the nature, significance and meaning of these elements (Burns & Groove, 2009:602). A satisfactory informed consent process for clinical research can be elusive under the best of circumstances and the prospective participants may be limited in their understanding of the process by poor education or serious illness (Morreim, 2004:1).

According to Lidz (2006:536), adequate information (I) given to a competent individual (C) will yield understanding (U), and a voluntary individual (V) who understands (U) will make a free and rational decision (D). This model is classic Enlightenment rationalism: if we are told the truth, we will be able to make rational decisions in our own best

interests. The model describes the ‘‘strong’’ version of informed consent in two formulae:

I+C =U

V+U=D

2.7 Therapeutic misconception

Therapeutic misconception (TM) was first identified by Appelbaum, Roth and Lidz in their influential 1982 paper (Lawrence, 2008:140). Therapeutic Misconception (TM) is when research participants cannot distinct between research and treatment. Lidz (2006:540) posit that TM is more than a failure by a subject to understand the elements of research consent. The subjects may not understand the nature of a study or the procedures involved but avoid attributing therapeutic intent to the research.

According to Henderson, Churchill, Davis, Easter, Grady, Joffe et al (2007:1735) the key component of informed consent to participate in medical research is the understanding that research is not the same as treatment. King, Henderson, Churchill, Davis, Hull, Nelson et al (2005:5) in an analysis of consent forms revealed that vagueness, inconsistency and overstatement may all promote confusion about what subjects can expect from receiving the experimental intervention. In this case participants may join studies with an idea that it is therapy meanwhile it is just research, especially in trials that compare treatment and placebo.

Conversely, understanding the goals and methods of a research project (e.g. double-blind procedures) does not mean that subjects will not attribute therapeutic motivations to them (Lidz, 2006:540). Henderson et al, (2007:1736) have documented misunderstanding among research participants being related to characteristics such as older age, lower education, and the way in which information about the study is conveyed.

2.8 Ethical considerations for IC

According to Iltis (2004:10) the existing theoretical understanding of the ethical requirement to obtain IC generally is understood as a duty to respect autonomy. That is the authority of persons to make decisions regarding what they will do and what will be done to them.

The GCP guidelines stipulates that, for an Informed consent form to be used in a trial, it must first be approved by an Institutional Review Board (IRB) or an Independent Ethics Committee (IEC). The IRB/IEC is independent body whose purpose is to ensure the safety and wellbeing of research participants. After approval by the IRB/IEC, the investigator or a person designated by the investigator is responsible to explain the informed consent, both in written form and orally, in a lay language. After receiving the information the research participant should be given time to consider the participation and if desired, discuss the participation with anyone they feel like (South Africa Department of Health, 2006).

When signing the informed consent form, the participants attests that the information has been explained and that they have understood the concepts. When the subject is not able to make an informed consent, the subjects' rights can be overtaken by a legally acceptable representative. This may be the case when children or psychiatric patients are enrolled in a trial. After signing the form, the participant should be provided a copy. Since Informed consent is a process, changes may be needed during the course of the trial. Any additional changes that may occur should be approved by the IRB and notified to the subject (South Africa Department of Health, 2006).

There are ethical aspects that need to be complied with when giving informed consent and are as follow;

2.8.1 Language

The form and the content for IC are influenced by the possibilities and limits of language (Marshall, 2007:31). The misunderstanding and miscommunication about the elements of IC are more likely to occur when investigators and participants speak different languages and when IC must be translated. In addition to the lack of equivalent or similar words that may be used in translation, the process of translation itself may result in misinterpretation of the research.

According to Mills et al (2006:309), obtaining consent is a further challenge in some female populations and that may interfere with their understanding of the uncertainties that exists within clinical trials. Furthermore Mills et al (2006:309) suggest all trial related information should be presented in the local language and should address varying levels of education in both written and oral presentation so that participants fully understand their rights, risks, benefits and potential benefits. This is further supported by the GCP guidelines that the language used in the oral and written information about the trial, including the written IC form, should be non-technical, practical and understandable to the subject or the subject's legally acceptable representative and impartial witness where applicable (South Africa Department of Health, 2006).

2.9 Vulnerable populations

The vulnerable populations are persons who are relatively or absolutely incapable of protecting their own interest through negotiations for informed consent (Tait, 2009:59). Those generally accepted as being vulnerable include children, prisoners, pregnant women, foetuses, mentally disabled persons, and economically or educationally disadvantaged individuals. These populations were identified after the historical examples in which research subjects were exploited for the purpose of medical research.

In addition Mkandawire-Valhmu, Rice and Bathum (2009:1729) suggest that it is important to consider that members of lower social economic background may participate in research out of obligation to the researcher whom they see as privileged than themselves. Furthermore Tait (2009:63) illustrates that patients with severe poorly controlled pain may experience limitations in autonomy and may misperceive benefits and risks.

Vulnerable populations refers to those that are at risk of being misused in the course of medical research, either by coercion or a lack of knowledge, understanding or ability to obtain and understand that knowledge presented before them.

In a study of mothers' experiences enrolling their children in bone marrow transplantation, it was found out that the women were emotionally traumatized by the news of finding out the diagnosis of their children and they could do anything in desperation for their children to get help (Stevens & Pletsch, 2002 :84). The perception of their medical condition that brought them to hospital was so critical and a matter of life and death that participation in the study was no longer a voluntary choice. They compromised their right of choice as they felt that if they decline to participate it may be just as good as sentencing one to early death. Furthermore Stevens and Pletsch, (2002:85) state that the mothers were prone to resentment, regrets and self-doubt particularly at turning points in the bone marrow transplant process.

2.10 Socio economic status

The men that participated in the Tuskegee Syphilis Experiment were typically poor and illiterate and this made it easier to deceive and exploit them (Sharma, 2009:256). When they were recruited they were also offered various incentives such as "free physical examinations", free rides to and from the clinics, hot meals on examination days, free

treatment for minor injuries, and a guarantee that burial stipends would be paid to their survivors (Sharma, 2009:256). This is coercion since they were poor it's obvious they would not miss such an opportunity for free food and free physical examinations. The participants' enrolment in this situation is evident that they did not understand the implications of the study but were after free medical services offered. Their social circumstance had more influence in their decision making. Thus socio-economic status plays a role in clinical research and can lead to misconceptions.

2.11 IC and Culture

In a study carried out in Botswana by Shaibu (2007:505) participants preferred to be interviewed together with family members who were considered to be contributing in their care-giving. The participants interpreted that care giving is not an individual effort but a collaborative endeavour within the extended family. According to Shaibu (2007:505) this view is deeply embedded in culture of Batswana people. This can be a concern of compromise of confidentiality. Moreover Frimpong-Mansoh (2007:108) believes that African culture places more emphases on community than the individual while the western values are individualistic.

According to Tindana, Kass and Akweongo (2006:1) in the Kassena–Nankana district of Northern Ghana, local cultural values and practices such as the role of traditional chiefs, influence many aspect of daily life including participation in research. Moreover in this society, husband' permission is likely to influence the female's decision to participate likewise in the community, if the chief gives a go ahead to the researchers to carry out the study (Tindana et al, 2006:5).

Cultural impacts are a challenge in some parts of the world when handling IC. In a study carried out in Nigeria, some patients view the fact that the doctor asked them to make a choice as a sign of incompetence (Ezeome & Marshall, 2009:142). Carrying out research in such populations will remain a challenge because IC must be choice without coercion.

IC is mostly carried out by nurses. In hospitals before any procedure is done on a patient for example operations, delivery of a baby using aid of instruments like forceps, an informed consent must be carried out. When treatment is provided to the patients, the nurse must inform the patient before giving and it's the responsibility of the nurse to answer any questions the patient may ask regarding the particular treatment. However if unsure of the answers he/she can consult the doctors for assistance.

2.12 Summary

This chapter is an over-view of the literature on IC. It points out the challenges that exist in the process of informed consent. Furthermore the manner in which information is communicated and how it influence understanding as well as cultural background' impact on IC.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

This chapter provides an overview of the research methodology used in this study. The description of the study design is made including its advantages and disadvantages. The study population, sampling method, data collection procedure are described. Furthermore data analysis, validity and reliability of the study and ethical consideration are also discussed.

3.2 Study Design

Burns and Grove (2009:696) describe a research design as a “blueprint for conducting a study that maximizes control over factors that could interfere with the validity of the findings” and research methodology as the “process or plan for conducting specific steps of the study”.

The study design was descriptive and methodology was quantitative. A survey was conducted to find out how well participants understood informed consent when participating in research.

3.2.1 Quantitative research

Quantitative research is the investigation of phenomena that lend themselves to precise measurement and quantification, often involving a rigorous and controlled design (Polit & Beck, 2006:508). Data that is quantified in quantitative research include variables such as weight, length, treatment outcome and gender.

3.2.2 Descriptive Design

Descriptive studies are used to identify phenomenon of interest, identify variables within the phenomenon, develop conceptual and operational definitions of variables and describe them (Burns & Groove, 2003:480). In a descriptive study, no attempt is made to change behavior or conditions, things are measured as they are.

3.2.3 Survey study

Survey studies can be classified as descriptive, exploratory or comparative (LoBiondo-Wood & Haber, 2010:198). These studies collect detailed descriptions of existing variables and use the data to justify and assess current conditions to make more plans for improving health care practice (LoBiondo-Wood & Haber, 2010:587). The main advantage of surveys is that they are inexpensive to conduct.

3.3 Study population and sampling

The study was carried out in a city located in the Eastern Cape Province of South Africa. Participants were recruited from clients who were participating in existing studies conducted at a research unit located at two hospitals in the city. There were three studies taking place at the research unit during the time of data collection. Participants were recruited from individuals who have already consented to participate in one of the research unit studies. Convenience sampling was used to select participants for the study. Each newly recruited participant who agreed and gave consent to participate in the research unit studies, was also approached to participate in this study.

Participants were recruited from the following studies:

Study A

Study A was a randomized controlled trial comparing the efficacy, safety and acceptance of the intra-uterine contraceptive device versus intramuscular depot progestogen contraception injection for reducing pregnancy rate.

Study B

The primary objective of study B was to explore the demographic, socioeconomic factors, infant feeding practices, immunisation, and micronutrient status on infant growth, diarrhoea as well as respiratory diseases in infants of age six weeks to nine months.

Study C

The primary objective of study C was to compare massaging the uterus for 30 minutes versus oxytocin injection in the prevention of post-partum haemorrhage.

3.4 Data collection Method

A questionnaire was formulated based on the template of the World Health Organization's template for informed consent. The questionnaire had both closed and open-ended questions. The open ended questions allowed participants to express themselves freely to explain what they understood from their participation in the trial. Additional baseline demographic data like age and educational background were also collected. The researcher and trained field workers were involved in the data collection process. All the field workers were trained in good clinical practice.

3.5 Questionnaire

The questionnaire consisted of 32 questions divided into five categories: biographical data, participation, intervention, risks/benefits and rights/obligations. The biographical part focused on the participants' age, gender, education etc. In the category of participation the questions considered the understanding of the purpose of the study and the reason for participating. The third category, intervention, explored the understanding of the procedures in the particular trial. The risks/benefits category focused on potential harms and whether participants expected any remuneration from participation. The last category rights/obligations focused on understanding of the possibility to withdraw, participants' awareness of what their signature on the consent form meant. The questions were based on an informed consent form which in turn was based on the WHO template for what kind of information an informed consent form should contain.

3.5.1 Advantages of a questionnaire

The questionnaires allows confidentially and anonymity (LoBiondo-Wood & Haber, 2010:277). Polit and Beck (2006:296) adds that anonymity may be crucial in obtaining information about illegal or deviant behaviours. Questionnaire excludes personal opinions' influence by data collectors on participants. Participants are free to write what they want at their own pace.

Generally it is quick to collect information using a questionnaire and potential information can be collected from a large portion of a group although it may take time to develop and analyse. The data collector was able to hand out about three questionnaires to three participants at the same time, unlike face to face interview where each participant is attended to solely.

The questionnaire was appropriate to use as the study was carried out mostly on women who were participating in the research unit studies and most of them were mothers with very young babies. It gave them time to be able to concentrate on their children as well and continue answering the questionnaire when finished with the baby.

3.5.2 Disadvantages of a Questionnaire

The people with lower literacy may have difficulty to complete (LoBiondo-Wood & Haber, 2010:277). Participants may forget important issues as questionnaires like other evaluation methods occur after the event.

The open-ended questions can generate large amounts of data that can take a long time to process and analyse. Participants may also answer superficially, more especially if the questionnaire is long. Where there is no clarity it is difficult to contact the participants unlike face to face interviews where one can seek clarity as the participant provide their views.

3.6 Procedure

Before participants were enrolled in their original study, the participants were given a hard copy of the informed consent form to read through. Since English and Xhosa are the most commonly spoken languages in the Eastern Cape, the informed consent form was available in both languages. The IC information was also given orally by members of the research team. After time had been given to consider the participation and ask questions regarding any aspect of the trial, the consent form was signed.

Within 48 hours, after participating in any of the 3 studies previously stated, the participants were asked to participate in the informed consent study. The minimum time interval between enrolment in the research unit studies and the IC study was eight hours. Participants were given time to consider their participation and ask questions regarding their participation in the informed consent study. If they agreed to participate and the informed consent form was signed they were handed a questionnaire. The questionnaire, containing questions regarding the original study, was then filled in by the participant. The filled in questionnaire was then collected and filed in a safe place.

The participant was given the opportunity to write down the answers to the open ended questions herself and had alternative of researcher to write down the answer. In the latter case the researcher read the documented answer back to the participant to

ensure correctness of the recorded information. The answers to the open ended questions were translated from Xhosa to English and back translated by a professional linguistic department to ensure accuracy of the information.

3.7 Data Analysis

Data analysis reduces, organizes and gives meaning to the data collected in a study (Burns & Groove, 2009:44). Quantitative data was entered onto a Microsoft excel sheet and analysed. Findings are presented in tables and texts, interpreted and discussed. The statistic test used was Chi-square to measure heterogeneity. The common themes and written descriptions of findings were formulated from responses of open-ended questions to analyze the responses of participants.

3.8 Reliability

Reliability is concerned with the consistency of the measurement technique (Burns & Groove, 2007:364). The reliability of the IC study was ensured by the guidance of the statistian who examined and approved the data collection tool. The data collectors were trained research midwives of the effective care research unit who passed the GCP course and researcher in addition collected data. The data collectors were also taught about the study and procedures of how the study should be carried out.

3.8.1 Reliability from data collectors

All the research midwives had undergone Good Clinical Practice training and were certified. Regular interaction of research midwives was encouraged and they were motivated to give correct information.

3.9 Validity

Validity refers to the degree to which the instrument accurately reflects the abstract concept being examined (Burns & Groove, 2007:365). A pilot study was conducted to test the questionnaire and to check the feasibility of the study prior to commencing data collection of the main study. The validity was ensured in the following manner;

3.9.1 Face validity

Face Validity is the verification that the instrument measures the content desired (Burns & Groove, 2007:540). The research instrument was introduced to the research unit staff and discussed with all the research midwives. For the purpose of the study, the instrument was pretested, through a pilot study, and all relevant questions were used in the actual study, after the removal of duplicated and unclear questions. .

3.9.2 Construct validity

The questionnaire was given to five experts to confirm, face, content and criterion validity. The questionnaire was first translated into Xhosa and then given to another translator and translated it back into English, assuring the accuracy of translation.

3.9.3 Content validity

The content validity is the extent to which the method of measurement includes all the major elements relevant to the construct being measured (Burns Groove, 2007:535). A thorough literature review was done by the researcher on all the aspects that can affect understanding of informed consent and a World Health Organisation (WHO) informed consent template was adapted to ensure that the instrument is comprehensive and represents a variety of knowledge in order to measure the question to be answered. The questions in the questionnaire were derived from its content. The WHO template contains all relevant aspect that needs to be addressed to participants.

3.9.4 External validity

The external validity had limitations in that the sample to a large extent consisted of low educated people living in townships in the city. This may make the results less reliable when generalizing the results to more developed parts of the world. However the results can be generalized to population where participants were drawn from.

3.9.5 Internal validity

Internal validity / truth-value was insured by being satisfied that the participants accurately understood the questions and agreed with the way it was interpreted. The researcher clarified the information given to her with the participant to ensure that it was correctly understood.

3.9.6 Validation of data collected

A daily review of data collected was conducted by the researcher and forms were dated, coded, and signed. The study faced a few biases; mainly information bias where by the participants may have answered in an attempt to please the researcher. Data collectors were trained on administering of the questionnaire and what the study is about.

3.10 Pilot Study

A pilot study is a smaller version of a proposed study which is conducted to refine the methodology such as the treatment, instrument or the process of data collection (Burns & Groove, 2009:44). The pilot study was conducted under similar conditions of the actual study. The questionnaire was issued to a smaller group of participants to check for weakness and vagueness. Only ten participants enrolled in the pilot study. The outcomes of the pilot study showed that the study was feasible and all errors were eliminated from the questionnaire of the actual study. The participants of the pilot study were not included in the analysis of the actual study.

3.11 Limitations

The limitation of this study included recruitment from only two maternity hospitals in one city, clients at other maternity units were not included in the study. Majority of the population was African, Xhosa women. Other racial groups were not well represented and require further investigation.

Another factor that influenced the results is that the questions in the questionnaire were based on a template for informed consents provided by WHO, however only one of the

original studies consent was based on the same template. The information on the duration of the original study was not included in all the three ICs of individual research unit studies and therefore made it impossible for the participants to give a correct answer.

3.12 Ethical considerations

This study was approved by Stellenbosch University HREC and permission to carry out the study was also obtained from the research unit which is based in two hospitals in the city. Confidentiality was maintained. Participants were free to decline or withdraw at any time and were assured that it would not compromise the care they received at the institution. Number codes were used for participants. No names were attached to participant's results even during report writing. The study was conducted according to the Good Clinical Practice guidelines in the conduct of Clinical Trials with Human participants.

3.13 Summary

The research design, data collection and procedures were addressed in this chapter. The reliability and validity of the data collection instrument were substantiated. In the following chapter findings of the study results are presented.

CHAPTER 4

RESULTS

4.1 Introduction

In this chapter the results of the research study are presented. The findings presented, report on the communication and miscommunication of informed consent in clinical trials. The results of both ended questions and close ended questions are provided in tabular form.

The sample size consisted of 170 participants from three groups of the research unit studies. The sample sizes were as follows; Study A (70 participants), Study B (20 participants) and Study C (80 participants).

The Chi-square test was applied to measure heterogeneity. The higher the Chi-square test the wider the differences of values or the wider the variation between groups. The p-value was set out at a significant level of 0.05 and therefore p-values of less than 0.05 were considered significant.

4.2. Ages of the three study groups

The ages of the participants from all the study groups are presented in Table 4.1. The research unit study groups are presented in the table. The age of participants ranged from 17 to 42 years old. The average age was 25.9 years with a standard deviation of 5.98 years.

Table 4.1 Ages of three study groups

VALUES	Study A	Study B	Study C	TOTAL
Average age	25.9	23.7	26.5	25.9
Std Dev	6.00	4.52	6.21	5.98
Min age	17	18	18	
Max age	39	32	42	
NUMBER OF PARTICIPANTS	70	20	80	170

4.3 Educational level of the participants

According to Table 4.2, the highest level of education for the majority was secondary level of education (n=114). Forty-two participants had a tertiary level of education and seven had primary level of education at the time of data collection. Only one participant never attended school.

Table 4.2 Educational level of the participants

EDUCATION	Study A	Study B	Study C	TOTAL n (%)
Tertiary	24	3	15	42 (24.7)
Secondary	45	14	55	114 (67.1)
Primary	1	3	7	11 (6.5)
Never attended school	0	0	1	1 (0.6)
No response	0	0	2	2 (1.18)
TOTAL	70	20	80	170

4.4 Working participants before pregnancy

The majority of the participants (n=111) were unemployed before the current pregnancy (see Table 4.3). Eighty percent of study A participants were not working before the pregnancy. In study B there was an equal number of people who were working before pregnancy and those who were not working while 56% of study C participants were not working before pregnancy.

Table 4.3 Working participants before pregnancy

WORK BEFORE	Study A n (%)	Study B n (%)	Study C n (%)	TOTAL n (%)
No	56 (80)	10 (50)	45 (56)	111 (65.3)
Yes	14 (20)	10 (50)	35 (44)	59 (34.7)
TOTAL	70	20	80	170

Test statistics Chi-squared=11.6325 p-value=0.003

4.5 Participants in pain when obtaining of Informed Consent

Ninety-five (55.9%) of the participants reported not being in pain during the time of signing an IC of the original study. In study A, study B and study C, 14.3%, 30% and 72.5% respectively reported not being in pain.

Table 4.4 Participants in pain when obtaining of Informed Consent

IN PAIN	Study A n (%)	Study B n (%)	Study C n (%)	TOTAL n (%)
No	60 (85.7)	14 (70)	21 (26.3)	95 (55.9)
Yes	10 (14.3)	6 (30)	58 (72.5)	74 (43.5)
No response	0	0	1 (1.25)	1 (0.6)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 54.4751, p-value = 0.00

4.6 Participants who were given a copy of Informed Consent

Five participants did not report whether they were provided with a copy of an IC. A total of 130 (76.5%) participants indicated that they received a copy of the IC whilst 35 (20.6%) did not. More participants who received a copy of the IC were those who were participating in the study A.

Table 4.5 Participants who were given copy of IC

GIVEN A COPY	Study A n (%)	Study B n (%)	Study C n (%)	TOTAL n (%)
No	2 (2.9)	6 (31.6)	27 (35.5)	35 (20.6)
Yes	68 (97.1)	13 (68.4)	49 (64.5)	130 (76.5)
No response	0	1	4	5 (2.9)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 24.6505 p-value = 0.001

4.7 Participants who were given opportunity to discuss participation with partner

According o Table 4.6, four participants did not indicate if they were given the opportunity to discuss with the partner or not. Approximately half (49.4%) were not given opportunity to discuss participation with their partners. The study C group had a much lower proportion (n=24) of people who had opportunity to discuss the IC of the original study with partner.

Table 4.6 Participants who were given opportunity to discuss participation with partner

OPPORTUNITY TO DISCUSS PARTICIPATION	Study A	Study B	Study C	TOTAL n (%)
No	23	8	53	84 (49.4)
Yes	47	11	24	82 (48.2)
No response	0	1	3	4 (2.4)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 19.6031 p-value = 0.0001

4.8 The reasons why subjects agreed to participate in the studies

Majority of the participants (n=144) had knowledge of why they agreed to participate in the original studies. Only 8.8% did not know why they agreed to participate. The type of study influenced why the participants agreed to participate in the three studies. There was a wide variation on responses between the groups (see Table 4.7).

Table 4.7 The reasons why subjects agreed to participate in the studies

WHY AGREED	Study A	Study B	Study C	TOTAL n (%)
Don't know	4	3	8	15 (8.8)
Knowledge	39	10	17	66 (38.8)
Treatment given	23	3	36	62 (36.5)
Other reasons	1	2	13	16 (9.4)
No response	3	2	6	11 (6.5)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 70.4764 p-value = 0.00

4.9 Participants' knowledge of the purpose of the studies

According to Table 4.8, the participants who did not have knowledge of the purpose of the original study were more than half (57%). Among the participants from study B, only five gave a closer answer. A total of 35 from study A also gave a closer answer as well as 26 participants from study C. None of the participants gave a correct answer.

Table 4.8 The purpose of the studies participants enrolled in

PURPOSE OF THE ORIGIONAL STUDY	Study A	Study B	Study C	TOTAL n (%)
Baby's health	0	5	2	7 (4.1)
Don't know	13	1	17	31 (18.2)
Easy pain	0	0	4	4 (2.3)
Family planning	35	0	0	35 (20.6)
Reduce bleeding	0	1	26	27 (15.9)
No response	22	13	31	66 (38.8)
TOTAL	70	20	80	170

4.10 Reasons why participants qualified to participate in the studies

The participants had no knowledge why they enrolled in the studies. Thirty-two (18.8%) participants did not respond while 135 (79.4%) gave uninformative responses. Only three (1.8%) participants from study A had knowledge of why they qualified. All three participants stated that it was because of their age. It is correct to say they qualified because of their age, as it was one of the inclusion criteria of the original studies.

4.11 The responsibility of participants during process of study.

The majority of the participants did not have knowledge of their responsibilities. A total of 73 (42.9%) participants gave uninformative responses, 45 (26.5%) indicated that they did not know their responsibilities and the rest (13.5%) did not respond. Only 29 (17.1%) participants had knowledge of their responsibilities, which was to cooperate and understand (see Table 4.9).

Table 4.9 The responsibility of participants during process of study.

RESPONSIBILITY	Study A	Study B	Study C	TOTAL n (%)
Cooperate	9	2	12	23 (13.5)
Don't know	26	1	18	45 (26.5)
Uninformative	29	12	32	73 (42.9)
Understand	4	0	2	6 (3.5)
No response	2	5	16	23 (13.5)
TOTAL	70	20	80	170

4.12 Informed of duration of study

Ninety-four (55.3 %) participants indicated that they were informed about the duration of the study. However information about the total duration of the original studies was not included in the IC forms of all the three original studies of the research unit. Sixty-seven (39.4%) participants indicated that they were not informed.

Table 4.10 Informed of duration of study

DURATION OF STUDY	Study A	Study B	Study C	TOTAL n (%)
No	18	9	40	67 (39.4)
Yes	50	10	34	94 (55.3)
No response	2	1	6	9 (5.3)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 11.3903 p-Value = 0.0034

4.13 If informed of duration of study, mention when it will end

Sixty-two (36.5%) participants did not respond to the question pertaining to whether they were informed of when the study would end. A total of 108 (63.5%) participants gave various answers. However the information of how long the study will take was not provided in all IC forms of the three studies.

4.14 The duration of participation on the studies

According to Table 4.11, thirty-two (18.8%) participants stated that they did not know the duration of their participation in the study. Fourteen (8.2%) participants gave uninformative responses and 32 (18.8%) did not provide response. Only 50 (29.4%) participants had knowledge of the duration of their participation in the studies, and they were all participants from study A.

Table 4.11 The duration of participation on the studies

DURATION	Study A	Study B	Study C	TOTAL n (%)
1 Visit	13	0	0	13 (7.6)
1 year	40	0	0	40 (23.5)
5-30 min	0	6	23	29 (17.1)
Don't know	5	1	26	32 (18.8)
Uninformative	2	5	7	14 (8.2)
Many visits	10	0	0	10 (5.9)
No response	0	8	24	32 (18.8)
TOTAL	70	20	80	170

4.15 Awareness of different treatments

A total of 86 (50.6%) participants responded that they were aware of the different treatments. Sixty –nine participants indicated that they were not aware of the different treatments. Fifteen (8.8) participants did not provide response if they were aware of the different treatments of the original study.

Table 4.12 Awareness of different treatments

AWARENESS OF DIFFERENT TREATMENT	Study A	Study B	Study C	TOTAL n (%)
No	8	8	53	69 (40.6)
Yes	62	3	21	86 (50.6)
No response		9	6	15 (8.8)
TOTAL	70	20	80	170

Test Statistic Chi-Squared = 56.5838 p-value = 0.00

4.16 The different treatment options or interventions

Sixty-four (37.6%) participants had the knowledge of the different treatments available. Fifty-seven participants (33.5%) were from study A and seven participants (4.1%) from study C. A total of 106 (62.4%) participants did not have knowledge of the treatment options, including 86 (50.6%) participants that did not provide a response (see Table 4.13).

Table 4.13 The different treatment options or interventions

INTERVENTIONS	Study A	Study B	Study C	TOTAL n (%)
Loop ,injection	57	0	0	57 (33.5)
Supplement, bottle or cup feeding	0	0	0	0 (0)
Massage/no massage	0	0	7	7 (4.1)
Incorrect answer	5	2	13	20 (11.8)
No response	8	18	60	86 (50.6)
TOTAL	70	20	80	170

4.17 Randomization

None of the participants knew anything about the chances of receiving any of the treatments. Uninformative answers were provided.

4.18 Benefits

The majority of participants (n=165) did not have knowledge of the possible benefits available of the original study. Thirty-nine participants indicated that they did not know the benefits. A total of 18 participants did not respond. Hundred and forty-seven (86.5%) participants gave uninformative responses. Only five participants had knowledge of the possible benefits available of the three studies.

4.19 Awareness of risks related to treatments or procedures

According to Table 4.14, 128 (75.3%) participants indicated that they had no knowledge of risks related to the treatments or procedures. A total of thirty-six (21.2%) participants indicated that they were aware.

Table 4.14 Awareness of risks related to treatments or procedures

AWARENESS OF TREATMENT RELATED RISK	Study A	Study B	Study C	TOTAL n (%)
No	48	10	74	128 (75.3)
Yes	22	10	4	36 (21.2)
No response	0	0	6	6 (3.5)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 31.6589 p-value =0.00

4.20 Risks related to the original study

Hundred and thirty-seven (80.6%) participants did not respond to the question pertaining to mentioning of the possible study related risks. However 36 (21.2%) participants stated in the previous question that they were aware of the study related risks but a lesser number (n=33) responded to the question. A total of nine participants from the 33 participants had knowledge of the possible risks related to the study.

4.21. Alternatives to participation

A total of 79 (46.5%) participants indicated that there were no alternatives available if one disagree to participate. Thirty-three (19.4%) participants had no knowledge of alternatives available if they disagree to participate. Only four (2.4%) participants had knowledge of the alternatives to participation if they disagree to participate in research unit studies. Twenty-two (12.9%) did not respond. Two (1.2%) participants stated that they did not understand. Thirty (17.6%) participants gave uninformative response.

4.22. Rights to withdrawal from the studies

Hundred and twenty-eight (75.3%) participants indicated that if they chose to withdraw from the studies there would be no consequences while thirty-two (18.8%) indicated that there would be consequences. Ten (5.9%) participants did not respond.

Table 4.15 Rights to withdrawal from the studies

ANY CONSEQUENCES OF WITHDRAWAL	Study A	Study B	Study C	TOTAL n (%)
No	56	12	60	128 (75.3)
Yes	14	7	11	32 (18.8)
No response		1	9	10 (5.9)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 4.2698 p-value = 0.1183

4.23 The consequences of withdrawal from the studies

Hundred and thirty-six (80%) participants did not provide response as to whether there would be any consequences if one chose to withdraw from the study. A total of 34 (20) participants responded but however the responses they gave were uninformative.

4.24 Any money received from the researcher

According to Table 4.16, 168 (98.8%) participants stated that they did not receive money from researcher. Only one (1.6%) participant stated that she received money from researcher. The participant did not provide the reason why she accepted the money and how much it was. There is no indication if it was related to enrollment of the study or personal. One participant (1.6%) did not respond.

Table 4.16 Any money received from the researcher

RECEIVED MONEY	Study A	Study B	Study C	TOTAL n (%)
No	70	19	79	168 (98.8)
Yes	0	1	0	1 (0.6)
No response	0	0	1	1 (0.6)
TOTAL	70	20	80	170

4.25 Trial related injuries

The participants were asked if they understand what assistance is available if they sustained an unexpected trial related injury. Twenty–five (14.7%) participants did not

respond. A total of (n=127) stated that they cannot recall. Only 18 (%) had knowledge of what will happen in an unlikely event.

4.26 Confidentiality

A total of twenty-two (12.9%) participants stated that nobody would have access to their personal information the researcher had about them. Twenty-four (14.1%) participants did respond to the question pertaining to who would have access to the information the researcher had about them. A total of 51(30%) stated that the medical team would have access to their information. Forty-eight (28.2%) participants stated that they did not have knowledge of who would have access to the information that they provided to the researcher. Twenty-five (14.7%) participants provided various responses which were incorrect.

4.27 The use of gathered information at the end of the study

Eighty-two (48.2%) participants stated that they did not have knowledge of what would be the use of the gathered information. According to Table 4.17, 62 (36.5%) provided uninformative answers. A total of 21 (12.4%) did not respond. None of the participants had knowledge of what would be the use of gathered information.

Table 4.17 The use of gathered information at the end of the study

INFORMATION GATHERED	Study A	Study B	Study C	TOTAL n (%)
Confidential	4	0	1	5 (2.9)
Don't know	30	6	46	82 (48.2)
Uninformative	32	11	19	62 (36.5)
No response	4	3	14	21 (12.4)
TOTAL	70	20	80	170

4.28 The person to contact for additional questions

According to Table 4.18, 61(35.9%) participants indicated that the research team could be contacted for additional questions, and additional 39 (22.9%) participants listed the medical staff (nurse and doctor). In total, more than half of the participants had knowledge of who to contact. Thirty-six (21.2%) participants did not respond. Three (1.8%) participants stated that nobody could be contacted for additional questions. Ten (5.9%) participant's responses were uninformative. Twenty one (12.4%) participants stated that they did not have knowledge of who to contact.

Table 4.18 The person to contact for additional questions

CONTACT PERSON	Study A	Study B	Study C	TOTAL n (%)
Don't know	2	0	19	21 (12.4)
Medical staff	33	2	4	39 (22.9)
Nobody	0	0	3	3 (1.8)
Research team	29	8	24	61 (35.9)
Uninformative	2	2	6	10 (5.9)
No response	4	8	24	36 (21.2)
TOTAL	70	20	80	170

4.29 The meaning of signature on IC

The majority of participants 115 (67.6%) stated that they understood what their signature on the IC of the original study meant. Less than half (27.6%) of the participants stated that they did not have knowledge of what their signature on the IC meant. Eight (4.7%) participants did not respond.

Table 4.19 The meaning of signature on IC

MEANING OF SIGNATURE	Study A	Study B	Study C	TOTAL n (%)
No	9	10	28	47 (27.6%)
Yes	58	9	48	115 (67.6%)
No response	3	1	4	8 (4.7%)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 15.305 p-value = 0.0005

4.30 Explanation of meaning of signature on informed consent form

Twenty-six (15.3%) participants had knowledge that their signature on the IC forms means their agreement to participate. Fifty-nine (34.7%) did not respond. Three (1.8%) participants responded that they did not know what it meant. The majority (144) did not have knowledge of what their signature on the IC form meant. These results contradict the total of 115 participants that indicated that they understand what their signature meant.

Table 4.20 Explanation of meaning of signature on informed consent form

EXPLANATION OF SIGNATURE	Study A	Study B	Study C	TOTAL n (%)
Agreement	18	2	6	26 (15.3)
Don't know	0	0	3	3 (1.8)
Family planning	10	0	0	10 (5.9)
Uninformative	29	7	17	53 (31.2)
Uterine massage	0	1	18	19 (11.2)
No response	13	10	36	59 (34.7)
TOTAL	70	20	80	170

4.31 Information given prior participation in the trials was sufficient or not

A total of 146 (85.9%) participants indicated that the information provided in the IC of the research unit studies was sufficient to decide to participate in the studies. Four (2.4%) participants did not respond. Only twenty participants stated that the information provided was insufficient. The responses of sufficiency of information was highly significant (p=0.0002).

Table 4.21 Information given prior participation in the studies was sufficient or not

INFORMATION SUFFICIENT FOR DECISION	Study A	Study B	Study C	TOTAL n (%)
No	0	4	16	20 (11.8%)
Yes	70	16	60	146 (85.9%)
No response			4	4 (2.4%)
TOTAL	70	20	80	170

Test Statistic Chi-squared = 16.5976 p-value = 0.0002

CHAPTER 5

DISCUSSIONS, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses the findings of this study. The conclusion and recommendations are provided. Obtaining an informed consent is an important ethical procedure in the process of a clinical trial. However, it is obvious that it has its limitations as observed in this study.

5.2 Age

The total average age of the study participants was 25.9 years. The studies at the research unit were mostly on reproductive health, and women of child bearing age participated. This explains the average age in this study. According to Kripalani, Bengtzen, Henderson, and Jacobson (2008:13) older age can adversely affect consent comprehension. However in this study age did not play a major role, consent was poorly understood across all ages (see annexure A).

5.3 Education

Level of education has been associated with understanding and comprehension of information. Sudore et al (2003:871) reported that lower literacy participants were at risk for poor comprehension of information.

The majority of participants in this study had secondary level of education. The literacy level of the study population was therefore average. Tertiary level consisted of 42 (24.7%) participants, secondary level had 114 (67.1%) participants and participants who had a primary level participants were 11 (6.5%). Kripalani et al, (2008:17) found that literacy was considerably associated with comprehension of consent and privacy of information, despite taking recommended steps to simplify the information. Additionally the participants of a higher educational level comprehend information better than those with lower grade (Kripalani et al, 2008:17). In overall the understanding of IC was very low. The questionnaire was poorly answered across all the educational levels.

Participant's responses showed a poor understanding of IC and this may be related to several factors. The most important factor is the language barrier between English speaking staff and participants whose parental tongue is Xhosa. Sudore et al (2003:871) identified that literacy and language barriers appear to be important determinants of comprehension of information.

To eliminate the language problem, questionnaires and IC's, were available in both Xhosa and English. When further oral explanation was needed the communication problem became obvious for non Xhosa speaking research staff, however Xhosa speaking staff were called to assist.

5.4 Pain

Pain can hinder understanding and impact on recalling of information depending on its severity. It has been illustrated by Tait (2009:63) that patients with severe poorly controlled pain may experience limitations in autonomy and may misperceive benefits and risks. A total of 74 (43.5%) participants were in pain during the time of obtaining consent. That might have had an impact on their understanding and recall of

information. Study C participants received IC of the original study in the labour ward. According to Jamieson, O'Sullivan, Maupin, Cohen, Webber, Nesheim, Lampe, Garcia, Lindsay and Bulterys, (2003:890), an informed consent process during labour, is difficult, physical and psychologically demanding. The women's attention and energies are mostly focused on the anticipated delivery and in most instances alleviation of pain.

5.5 Vulnerable population

The participants of study C were recruited while in labour. This might have influenced their patience to try and listen to the researcher and make an informed decision before joining the study. When taking note of the question that needed participants to explain what their signature meant on the IC, only 6 (7.5%) out of 80 participants from study C responded. A total of 74 (92.5%) out of 80 participants of study C could not give the appropriate answer. Pregnant women fall under the vulnerable populations. According to Tait (2009:63) the patient in severe poorly controlled pain may experience limitations in autonomy and may misperceive benefits and risks. The discomfort of labour pains might have influenced them to accede to study participation (Tait, 2009:70).

5.5.1 Socio-economic status

A total of 65.3% of the study population was unemployed before pregnancy. Employment was also used as an indicator of economic status. It has been documented that men that participated in the Tuskegee Syphilis Experiment were typically poor and illiterate and this made it easier to deceive and exploit them (Sharma, 2009:256). According to Mill et al (2006:308) women in poorer countries often lack formal education and may not understand the uncertainty or the risk that exists within clinical studies. In those communities mostly men are the ones responsible for providing for the family. Additionally it is important to consider that members of lower socio-economic strata may participate in research out of obligation to please the

researcher, who they see as possessing greater power and privilege than themselves (Mkandawire-Valhmu, 2009:1729).

5.6 Communication and Miscommunication

The information about the duration of the study was not included in all the three studies of the research unit informed consent forms. Some of the research midwives informed the participants verbally about the duration of the studies after being queried. Therefore it was impossible for the participants to know if uninformed. The poor understanding of certain questions may not always be due to poor understanding but rather the consequence of poorly communicated information. King et al (2005;6), in their analysis of consent forms reported that vagueness, inconsistency and overstatement may all promote confusion about what subjects can expect from receiving the experimental intervention. The majority of the participants (n=146) believed that the information given prior to participation was sufficient to make an educated decision but somehow it contradicts with the majority of questions which were poorly answered. However the participants acknowledged that information was sufficient. According to GCP guidelines (Department of Health, 2006) it is the responsibility of the researcher to make interaction between the participants, fruitful in a way that the participant attains understanding desired to make up an informed decision.

5.7 Comprehension of information

None of the participants knew anything about the chances of receiving any of the treatments. In general the participants did not understand randomisation. According to Cahana and Hurst (2008:448) subjects are more likely to misunderstand certain aspects specific to research such as randomization or double-blind design. Randomization is

quite complex for participants to understand, even though it was explained simply. Participants thought they had a choice of one of the treatments. In the recruitment of Study A, most participants were excluded because they requested for IUCD before randomization. The participants thought they could make a choice between the two treatments due to the misunderstanding of randomization.

5.8 Rights and obligations of participants

Hundred and nineteen, (70%) participants did not have an idea who would have access to the information the researcher had about them. This did not stop them from deciding on joining the research study. Participants were not concerned about the extent of confidentiality that they were entitled to. According to Mallardi, (2005:313), in the early times the relationship between doctor and patient was consolidated, it was based upon two very definite criteria. These include the professional duty of the physician to do what is best for the patient and the duty of the patient to completely accept the physician's decisions and intervention. The patients' doctors felt it was their duty to guide patients and make decisions as they viewed patients as ignorant and not interested in explanations concerning therapeutic effects (Mallardi, 2005:313).

5.9 Therapeutic Misconception

Some participants took part in the studies for therapeutic reasons and did not understand the nature of research. One participant eluded her participation in the study to easing of pain and preventing bleeding.

According to Appelbaum, Lidz and Grisso (2004:1) the participants frequently appear to overestimate the likely benefits of entry into research studies and underestimate risks,

to be confused about the nature of randomized assignment and generally to conflate research with ordinary treatment. Furthermore Appelbaum et al (2004:1) suggest that therapeutic misconception is not equivalent to simple failure to understand the nature and purpose of the research study or the procedures involved. The participants may fail to understand these aspects of the study without mistakenly attributing therapeutic impact to them.

The participants may understand the purpose and nature of the study but that does not mean they won't enrol in the studies without relating them to therapeutic intent. Some participants might have joined the study as a result of desperation for help. One of the participants responded that she joined the study "for pain relief" while another one's response was "I needed help". In a study by Stevens and Pletsch (2002:84) the parents of children with leukemia who had to undergo bone marrow transplant, the word study didn't mean anything to them. One of the mother's responses was "all I wanted was some way to get rid of the leukemia, so study or no study it does not matter, treat her and keep her alive" (Stevens & Pletsch, 2002:84).

5.9.1 Cosmetic

Some participants agreed to sign the informed consent of the original study for cosmetic reasons. One of the participants of Study C's response to the question pertaining to why she agreed to participate was "because I wanted a massage". This shows she was enrolling in the study for cosmetic intent, of a massage. The participant had a different perception or understanding of the IC of the study. Study C used deep subcutaneous massaging of the uterus to stimulate contractions and stop blood flow. The participant's misunderstanding of the purpose of the study might have been due to the manner in which the consent information was communicated or misunderstanding the research staff. In a study of analysis of 321 gene transfer research consent forms, it was reported that most participants were not given clear and unambiguous information about

potential benefits (King et al, 2005:5). According to Kimmelman (2007:36) research subjects mistakenly believe that research projects will directly benefit them. This is referred to as therapeautic misconception.

5.9.2 Socialization

Participants' involvement in the research unit studies by some was seen as a means of socialization, not understanding the main aim of the study which all research participants must consider before giving consent to join the research studies. One of the participants when asked the purpose of the study, her response was "I think is to socialize with people and to know me and my baby". Similarly Kimmelman (2007:36), suggest that research subjects mistakenly believe that research projects directly benefit them.

5.10 Provision of informed consent for the three studies

The data collectors were GCP trained research midwives working at the research unit. The research unit holds an annual research methods course for all the employees and any other interested individuals can attend. The course is comprehensive to ensure the employees understand the conduct of clinical trials and procedures. The operational manuals of the studies are explained to the research team and workshops are held before initiations of the studies. The research unit holds meetings every second week for discussion of progress of all studies taking place. The data collectors were free to consult the Principal Investigator on site for any uncertainties.

5.11 Conclusion

The aim of this study was to assess the understanding of information communicated to trial participants by means of an informed consent form. A signed informed consent does not guarantee that the participant has understood the information given and also pain significantly decreases a participant's ability to comprehend information. However no matter which parameter we look at, the overall understanding is very poor**.**

The informed consent process is the key tool for which the ethical aspects of clinical trials rely on. The need of developing this tool is clearly evident after reading the results of this study. The conditions under which this survey was made must be taken into account when applying the result to other populations. Some of the women who participated in the three studies were in pain. Being in such a state might have led to participants unconditionally putting their trust in research unit personnel. In spite the overall low understanding more than 80 % considered that the information given prior the original study was sufficient to make an educated decision. This may indicate that it is a difficult task to evaluate the process of informed consent in a fair way.

The questionnaire of the IC study contained too many questions. This made the process of completing the questionnaire to be time consuming. All questions were important questions. The reason for the questionnaire being so comprehensive was to increase the reliability and to cover all aspects in the WHO template for what information an IC form should contain.

5.11 Recommendations

The existing methods of communicating and obtaining of an informed consent seem to be insufficient for participants to make an informed decision. A new approach with more interactive features such as combination of audiovisual techniques might increase the possibilities of understanding. Recall might be improved if participants are provided with a video to watch prior to administration of a written consent. One is likely to remember what is seen than what is only heard or read. Administering of pamphlets with pictures and extensive teaching with posters prior to handing out of informed consent information leaflets also might be of help.

Enhanced consent documents should be provided at a lower level to accommodate lower literacy level participants. In addition, materials should be relatively short, clearly organized with subheadings, illustrated, and written with straight forward vocabulary.

In labour a woman is under very strong pain. This might have an effect on her conception of information provided during this period. It might be more ideal to provide most of the information during ante-natal classes than during labour.

Closer monitoring of the informed consent process may increase the will of researchers to conduct this process more rigorously. Participants of research must be given ample time to read and understand informed consent. Providing participants with information leaflet to take home to discuss with family members or friends before they join studies or alone, freely with no pressure of delaying data collectors is recommended.

The results indicated some gaps that exist during the process of obtaining consent. There may have been recall bias as some answers were not satisfactorily attempted.

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ANNEXURES A

Annexure Additional tables

Comparison of Age, Educational Level, Pain if they affect understanding

Selective comparison was done and the aim was to have homogenous groups to compare. The three variables, which are pain, educational level and age, were correlated with the ability to answer question pertaining to the knowledge of purpose of conducting the studies the participants enrolled in.

Explanation of study purpose: Study A

VALUES	CONTRACEPTIVES	DON'T KNOW	FAMILY PLANNING	NO RESPONSE	TOTAL
Count of Age	8	13	27	22	70
Average of Age	24.13	27.31	25.74	25.86	25.89
Std Dev of Age	4.61	5.47	5.57	7.30	6.00
Min of Age	*18*	17	18	17	17
Max of Age	31	36	37	39	39

Age did not play a major role in the reason comparing the average within the study A participants.

Explanation of study purpose: Study B

VALUES	BABY'HEALTH AND FEEDING	DON'T KNOW	REDUCE BLEEDING	NO RESPONSE	TOTAL
Count of Age	5	1	1	13	20
Average of Age	23.80	29.00	23.00	23.31	23.70
Std Dev of Age	5.54	0	0	4.42	4.52
Min of Age	*19*	29	23	18	18
Max of Age	32	29	23	32	32

Age did not play a major role in the reason comparing the average within the study B participants.

Explanation of study purpose: Study C

VALUES	BABY'S HEALTH & FEEDING	DON'T KNOW	EASE PAIN	REDUCE BLEEDING	UTERUS IN PLACE	LITTLE BLEEDING	NO RESPO-NSE	TOTAL
Count of Age	2	17	3	14	6	6	31	79
Average of Age	32.50	24.71	24.00	26.00	32.00	31.33	25.68	26.54
Std Dev of Age	0.71	5.60	3.46	6.18	6.54	5.32	6.16	6.21
Min of Age	*32*	18	22	18	24	25	18	18
Max of Age	33	37	28	37	40	39	42	42

Age did not play a major role in the reason comparing the average within the C study participants.

Tertiary educational level; explaining purpose of the study-Study C

VALUES	CONTRACEPTIVE	DON'T KNOW	FAMILY PLANNING	NO RESPONSE	TOTAL
Count of Age	5	3	10	6	24
Average of Age	25.80	25.00	24.50	25.67	25.13
Std Dev of Age	3.96	4.00	5.32	8.29	5.52
Min of Age	22	21	20	19	19
Max of Age	31	29	34	39	39

Secondary educational level; explaining purpose of the study-Study A

VALUES	CONTRACEPTIVE	DON'T KNOW	FAMILY PLANNING	NO RESPONSE	TOTAL
Count of Age	2	10	17	16	45
Average of Age	18.50	28.00	26.47	25.94	26.27
Std Dev of Age	0.70	5.83	5.75	7.19	6.33
Min of Age	18	17	18	17	17
Max of Age	19	36	37	37	37

4.38 Tertiary educational level; explaining purpose of the study-Study C

VALUES	DON'T KNOW	EASE PAIN	UTERUS IN PLACE/LITTLE BLEEDING	NO RESPONSE	TOTAL
Count of Age	5	1	1	8	15
Average of Age	28.00	22.00	32.00	30.13	29.00
Std Dev of Age	6.16	0	0	7.99	6.93
Min of Age	22	22	32	20	20
Max of Age	37	22	32	42	42

Secondary educational level; explaining purpose of the study-Study C

VALUES	BABY'S HEALTH & FEEDING	DON'T KNOW	EASE PAIN	REDUCE BLEEDING	UTERUS IN PLACE	LITTLE BLEEDING	NO RESPONSE	TOTAL
Count of Age	1	11	2	12	6	3	19	54
Average of Age	32	22.91	25.00	26.25	32.00	28.67	24.53	25.80
Std Dev of Age	0	4.99	4.24	6.08	6.54	5.51	4.64	5.75
Min of Age	32	18	22	18	24	25	18	18
Max of Age	32	34	28	37	40	35	38	40

Explaining purpose of the study: Study A participants NOT in pain

VALUES	CONTRACEPTIVES	DON'T KNOW	FAMILY PLANNING	NO RESPONSE	TOTAL
Count of Age	5	12	23	20	60
Average of Age	22.20	27.42	26.00	25.60	25.83
Std Dev of Age	4.32	5.70	5.49	7.32	6.12
Min of Age	*18*	17	18	17	17
Max of Age	29	36	37	39	39

Explaining purpose of the study: Study A participants IN pain

VALUES	CONTRACEPTIVES	DON'T KNOW	FAMILY PLANNING	NO RESPONSE	TOTAL
Count of Age	3	1	4	2	10
Average of Age	27.33	26.00	24.25	28.50	26.20
Std Dev of Age	3.51	0	6.70	9.19	5.51
Min of Age	*24*	26	19	22	19
Max of Age	31	26	34	35	35

Explaining purpose of the study:Study C participants NOT pain

VALUES	BABY'HEALTH & FEEDING	DON'T KNOW	REDUCE BLEEDING	UTERUS IN PLACE/LITTLE BLEEDING	NO RESPONSE	TOTAL
Count of Age	1	3	7	2	8	21
Average of Age	32.00	22.33	25.29	31.50	26.00	26.05
Std Dev of Age	0	3.21	7.30	0.71	7.07	6.45
Min of Age	32	20	18	31	18	18
Max of Age	32	26	37	32	42	42

Explaining purpose of the study: Study C participants IN pain

VALUES	BABY'S HEALTH & FEEDING	DON'T KNOW	EASE PAIN	REDUCE BLEEDING	UTERUS IN PLACE	LITTLE BLEEDING	NO RESPONSE	TOTAL
Count of Age	1	14	3	7	6	3	23	57
Average of Age	33	25.21	24.00	26.71	32.00	30.00	25.57	26.58
Std Dev of Age	0	5.95	3.46	5.31	6.54	7.81	5.98	6.12
Min of Age	33	18	22	18	24	25	18	18
Max of Age	33	37	28	31	40	39	42	42

Explaining purpose of the study: Study B participants IN pain

VALUES	DON'T KNOW	NO RESPONSE	TOTAL
Count of Age	1	5	6
Average of Age	29.00	21.20	22.50
Std Dev of Age	0	3.49	4.46
Min of Age	29	18	18
Max of Age	29	27	29

Explaining purpose of the study: Study B participants NOT in pain

VALUES	BABY'HEALTH AND FEEDING	REDUCE BLEEDING	NO RESPONSE	TOTAL
Count of Age	5	1	8	14
Average of Age	23.80	23.00	24.63	24.21
Std Dev of Age	5.54	0	4.63	4.61
Min of Age	*19*	23	20	19
Max of Age	32	23	32	32

STELLENBOSCH UNIVERSITY

FACULTY OF HEALTH SCIENCES, DIVISION OF NURSING

Site Number ☐☐☐ Study Number ☐☐☐

Informed Consent Study

Thank you for agreeing to participate in our Informed Consent study, which involves your understanding of the informed consent process.

Uvavanyo lweMvume ecingisisiweyo

Enkosi ngokuvuma ukuthatha inxaxheba kuphando lwethu olumalunga neMvume ecingisisiweyo, equka ukuqonda kwakho inkqubo yemvume ecingisisiweyo.

Biographical Data

1. How old are you? ☐☐

2. What is the highest education level that you have completed?

Please tick the box.

Tertiary level ☐

Secondary level ☐

Primary level ☐

Never attended school ☐

Other ☐

……

3. Have you been working in the year before you fell pregnant?

Yes ☐ No ☐

1. Mingaphi iminyaka yakho? ☐☐

2. Leliphi inqanaba eliphezulu lemfundo oligqibileyo?

Korekisha ibhokisi.

-Inqanaba lemfundo ephezulu ☐

Inqanaba lemfundo

-yamabanga aphakamileyo ☐

Inqanaba lemfundo

-yamabanga asezantsi ☐

Andizange ndaya esikolweni ☐

-Okunye ☐

……

3. Ubuphangela kunyaka ongaphambi kokuba ukhulelwe?

Ewe ☐ Hayi ☐

4. What work were you doing before you fell Pregnant?

Professional ☐

Domestic ☐

Shop Assistant ☐

Hawker ☐

Other ……..

All the questions we are going to ask you now are regarding to the consent form that you have signed when you agreed to participate in one of the Effective Care Research Unit - ECRU trials. That ECRU trial will from now on be referred to as the original study.

5. Please tick the ECRU study that you participated in.

PROMISE-PEP ☐

ECHO study ☐

AMTSL study ☐

NUFU surcey ☐

6. Were you in pain or in any other discomfort during the time that the researcher obtained the informed consent from you for the original study?

Yes ☐ No ☐

4. Ubusenza wuphi umsebenzi?

Oqeqeshelweyo ☐

Owokucoca ☐

Umncedisi evenkileni ☐

Umthengisi ☐

Omnye……

Yonke imibuzo esiza kukubuza yona ngoku imalunga nefomu yemvume oye wayisayina ngexesha ubuvuma ukuthatha inxaxheba kwelinye iCandelo loPhando loNonophelo oLuluncedo – uvavanyo lwe-ECRU. Uvavanyo lwe-ECRU ukusukela ngoku kuza kubhekiswa kulo njengophando lokuqala.

5. Korekisha uphando lwe-ECRU oye wathabatha inxaxheba kulo.

PROMISE-PEP ☐

Uphando lontswangciso ntsapho ☐

Uphando lokukhusela ukopha ☐

Uphengululo lwezondlo ezincinci ☐

6. Ingaba ubuqaqanjelwa okanye ubukuyo nayiphina imeko yokungonwabi ngexesha umphandi efumana imvume ecingisisiweyo kuwe yophando lokuqala?

Ewe ☐ Hayi ☐

7. If yes, do you think that the pain or discomfort influenced your decision to participate in the trial?

Yes ☐ No ☐

8. Have you been given a copy of the informed consent of the original study that you have agreed to participate in?

Yes ☐ No ☐

Participation

9. Were you given the opportunity to discuss the participation in the original study with your partner or confidant?

Yes ☐ No ☐

10. Why did you agree to participate in the original study?

……
……
……

11. Can you please explain the purpose of the original study?

……
……
……

7. Ukuba uthi ‘ewe’, ucinga ukuba iintlungu okanye ukungonwabi kuye kwanefuthe kwisigqibo sakho sokuthatha inxaxheba kolu vavanyo?

Ewe ☐ Hayi ☐

8. Uye wanikwa ikopi yemvume ecingisisiweyo yophando lokuqala oye wavuma ukuthatha inxaxheba kulo?

Ewe ☐ Hayi ☐

Uthatho-nxaxheba

9. Uye wanikwa ithuba lokuba uxoxe ngothatho-nxaxheba kuphando lokuqala kunye neqabane lakho okanye nomntu othembekileyo?

Ewe ☐ Hayi ☐

10. Kutheni ukuze uvume ukuthatha inxaxheba kuphando lokuqala?

……..
……....
……..

11. Ungakhe ucacise injongo yophando lokuqala?

……
……
……

12. If you know why, can you name the reason/s why you qualified to participate in the original study?

……..

……..

13. Can you mention your responsibilities (what was expected from you) during the original study?

……

……..

.....……

14. Do you know when the whole study (origional) will end ?

Yes ☐ No ☐

15. If yes, when will it be completed?

.....

.....

16. How long will <u>you</u> have to participate in the study? (1 visit or many visits)

.....

.....

12. Ukuba uyazi ukuba kutheni, ungakhe uxele isi/zizathu so/zokuba kutheni ukuze ukulungele ukuthatha inxaxheba kuphando lokuqala?

……

……

13. Ungakhe uxele uxanduva lwakho (yintoni ebilindelwe kuwe) ngexesha lophando lokuqala?

……..

……

……..

14. Uye waxelelwa ukuba luza kuthatha ixesha elingakanani uphando phambi kokuba lugqitywe?

Ewe ☐ Hayi ☐

15. Ukuba uthi ‘ewe’, luza kugqitywa nini?

.....

.....

16. Uza kuthatha ixesha elingakanani ekuthabatheni inxaxheba kolu phando?

.....

.....

Intervention (Randomized Control Trials only**)**

17. When you were asked to participate in study You were explained about two different treatments. Can you remember what the treatments were?

Yes ☐ No ☐

18. If yes, can you name them?

……
……

……

19. What do you understand about randomisation or random chance?

.....
.....

Ukuthatha inxaxheba (KokweeMvavanyo zoLawulo ezingaKhethiyo kuphela)

17. Ingaba ubusazi ngokhetho olwahlukeneyo lonyango okanye lokuthatha inxaxheba phambi kokuba usayine ifomu yemvume yophando lokuqala?

Ewe ☐ Hayi ☐

18. Ukuba uthi ‘ewe’, ibiloluphi ukhetho?

……
……
……

19. Ingaba yintoni oyiqondayo ngamathuba okufumana olunye lonyango?

.....
.....

Risks and benefits

20. What are the possible benefits of the original study to you?

.....
.....
.....

21. Are you aware of any risks related to The origional study?

Yes ☐ No ☐

Imingcipheko noncedo

20. Loluphi uncedo onokulufumana kuphando lokuqala?

.....
.....
.....

21. Ingaba unalo ulwazi lwemingcipheko enxulumene nalo naluphina unyango okanye iinkqubo?

Ewe ☐ Hayi ☐

22. If yes, can you mention some?

.....
.....
.....

Rights and Obligations

23. If you would not have agreed to take part in the original study, what alternatives did you have?

.....
.....
.....

24. If you choose to withdraw from the original study, will this have any consequences to you?

Yes ☐ No ☐

25. If yes, which consequences would it be?

.....
.....

26. Have you received any money from the researcher?

Yes ☐ No ☐

If yes, how much? R…….

If yes, why did you get the money?

……

22. Ukuba uthi ‘ewe’, ungakhe uxele olunye unyango okanye ezinye iinkqubo?

.....
.....
.....

Amalungelo neembophelelo

23. Ukuba ubungavumanga ukuthatha inxaxheba kuphando lokuqala, yeyiphi enye indlela obunayo?

.....
.....
.....

24. Ukuba ukhetha ukurhoxa kuphando lokuqala, ingaba oku kuza kuba neziphumo kuwe?

Ewe ☐ Hayi ☐

25. Ukuba uthi ‘ewe’, zeziphi iziphumo eziza kubakho?

.....
.....

26. Ingaba kukho imali oyifumene kumphandi?Ewe ☐ Hayi ☐

Ukuba uthi ‘ewe’, yimalini? R…….

Ukuba uthi ‘ewe’, bekutheni ukuze ufumane imali?

……

27. What do you understand regarding the help available in the unexpected event of any trial related injuries that may occur to you while in the trial?

.....
.....
.....

28. Who will have access to the information the researcher has about you?

.....
.....

29. Could you please explain what is going to happen with the information we have gathered when the study is completed?

……
……..

30. If you have additional questions original study, who would you contact (name not necessary)?

.....

31. Do you understand what your signature on the informed consent mean?

Yes ☐ No ☐

27. Wazi ntoni mayela noncedo olukhoyo ngemeko enokuvela yokonzakala okunokwenzeka kuwe okunxulumene nolu vavanyo, ngexesha ukolu vavanyo?

.....
.....
.....

28. Ngubani oza kufikelela kulwazi olumalunga nawe umphandi analo?

.....
.....

29. Ungakhe uchaze ukuba kuza kwenzeka ntoni ngolwazi esiye saluqokelela xa olu phando luphelile?

……..
……..

30. Ukuba uneminye imibuzo emalunga nophando lokuqala, ngubani oza kuqhagamshelana naye (igama aliyomfuneko)?

.....

31. Uyaqonda phofu ukuba utyikityo lwakho olukwimvume ecingisisiweyo luthetha ntoni?

Ewe ☐ Hayi ☐

32. If yes, can you explain what you signed for?

.....

.....

32. Ukuba uthi ‘ewe’, ungakhe uchaze ukuba ubusayinela/ubutyikityela ntoni?

……..

.....

33. Do you believe that the information given to you prior to the participation in the original study was sufficient to make an educated decision in participating in the trial?

Yes ☐ No ☐

33. Ingaba ukholelwa ukuba ulwazi onikwe lona phambi kokuthatha kwakho inxaxheba kolu phando belanele ukuba ungenza isigqibo esisiso sokuthatha inxaxheba kolu vavanyo?

Ewe ☐ Hayi ☐

Thank you for participating!

Enkosi ngokuthatha kwakho inxaxheba!

Name of investigator: …….

Name of original study (to be filled in by **researcher**): …….

Informed consent form for women who attend the East London Complex Hospitals and the health clinics in the Amathola district, and who are invited to participate in the following research project.

Name of Researcher: Gaotswake Patience Moloi

Name of Organization: University of Stellenbosch

Name of Proposal: Informed consent: communication and miscommunication in clinical trials

Version and date: July 2010

Ethics approval number: N10/02/025

This informed consent form has two parts:

Information sheet, where we share the information with you.

Certificate of consent, where you sign that you agree to participate.

Part 1 Information sheet

Introduction

Dear Ms……,My name is ……..

This study is part of Patience Moloi's research that leads toward a Master's degree, studying at the University of Stellenbosch and is currently doing a study on informed consent: communication and miscommunication in clinical trial in Buffalo Municipality.

We would like to share some information with you and invite you to participate in this research study. Before you decide to participate you can talk to anyone you feel comfortable with about the research, including your family if you wish to do so. There may be some words in this form that you do not understand. Please ask me to stop as we go though the information and I will take time to explain. If you have any questions later, you can ask me or any other member in the research team.

Purpose

The purpose of our study is to evaluate the understanding of informed consent when participants consent to partake in a clinical trial or any research study. We would like to find out if participants fully understand what an informed consent is and whether they understand why they agree to participate in a research study. We are concerned that participants may not always understand and we hope that this study will help us to find out how we can improve the concept of obtaining informed consent from participants.

Type of intervention

This is a descriptive survey and we will conduct an interview with you that will last for about 30 minutes. Your role for the purpose of this study is merely to answer a few questions regarding the consent form that you have signed for the clinical trial or survey that you are participating in.

Participant selection, Procedure and Protocol

The population will be all women participating in any of the Effective Care Research Unit (ECRU) studies. You have been invited to participate in this informed consent study because you have signed an informed consent form for a clinical trial in one of the ECRU trials. If you agree to participate in this study the researcher will ask you a few

questions and the answers will be written down on the data collect sheet, or alternatively if you can read and write will we ask you to complete the data form yourself.

Unfamiliar procedures

No unfamiliar procedures will be done other than to ask you some questions.

Duration

The interview that you will take part in will last approximately 30 minutes. The study, on the other hand, will last until the end of November in 2010.

Risks & Discomforts

There are no risks involved in participating in this study. There are no anticipated discomforts in this study.

Benefits

There is no direct benefit for you but your participation may improve our understanding of how well participants understood informed consent. There may not be any benefit to society at this stage of the research, but the results of this study may help us to determine if there are ways in which we could help research participants to understand informed consent better in the future.

Insurance

The execution of the research will comply with the World Medical Association's Recommendations guiding Physicians in Biomedical Research Involving Human Subjects, the Helsinki declaration and good clinical practice guidelines.

Confidentiality

It is possible that if others in the community are aware that you are participating in this research, they may ask you questions. We will not be sharing the identity of those participating in the research with anyone. The information that we collect from this survey will be kept confidential. Information about you that will be collected during the research will not be identified by your name. They questionnaires will be kept safely and your name will only be on the informed consent form. There will be an identifying number on the questionnaire to match the informed consent with the questionnaire. This is only for research purposes. No information gathered from you will be shared with or given to anyone other than the research team.

Sharing the Results

The knowledge that we get from doing this research will be shared with you before it is made widely available to the public. We will put notices up at the clinic that the results are available and where you can get the results. In addition there will be meetings in the community to share the results of the survey. The results will also be published in academic journals so that other interested people may learn from our research.

Voluntary participation and Right to Refuse or Withdraw

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive

at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed to participate earlier.

Alternatives to Participating

You may choose not to participate in the study but it will not affect you in any way as this is just a survey.

Ethical clearance

This proposal has been reviewed and approved by the Stellenbosch University Health Research Committee, as well as permission from the Research unit in the East London Hospital Complex. The purpose of these committees is to ensure that research participants are protected. If you wish to find about more about the IRB, contact Mandisa Singata, ECRU, Cecelia Makiwane Hospital, 082 420 1743.

Who to Contact

Ms Mandisa Singata: work 043 708 2134, home 043 708 2426, cell: 082 420 1743 or

email mandisa.singata@gmail.com, msingata@yahoo.com or Prof Dr Cheryl Nikodem at

082 339 1204.

You may contact them at any time if you have any questions related to this survey.

Before I ask you to sign this consent form, may I please ask you to explain to me in your own words what you have just read or what I have just explained to you. I would like to ensure that you understand that you agree to participate in research.

PART II: Certificate of Consent

I have been invited to participate in a study involving the understanding of informed consent:communication and miscommunication in clinical trials in the Buffalo municipality area, Amathole district, South Africa. I understand that there are no risks involved and I am aware that there may be no benefit to me personally and that I will not be compensated. I have been provided with the name of a researcher who can be contacted easily using the number and address I was given for that person.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this survey and understand that I have the right to withdraw from the research at any time without in any way affecting my or my infant's future health care.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

Print Name of Researcher_____

Signature of Researcher _____

Date _____

Day/month/year

If <u>illiterate</u> complete this as well:

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND

Thumb print of participant

Date _____

Day/month/year

Signature of witness _____

Date _____

Day/month/year

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Researcher_____

Signature of Researcher _____

Date _____

Day/month/year

An original copy of this Informed Consent Form has been provided to participant _____

An original copy of this Informed Consent Form will be filed in a secure place in the research unit _____

(Initialled by the researcher)

Iphepha Mvume Lomama abaze e East London Hospital Complex baza bathatha inxaxheba kwi zifundo zophando ezenziwa lisebe le effective care research unit.siyabamema ukuba bathathe inxaxheba kolu uphando lungezantsi:

IGama loMphandi: Gaotswake Patience Moloi

IGama loMbutho: IDyunivesithi Yase Stellenboch

IGama leSiphakamiso: Uphando olunqamleze amacandelo ukucacisa imiba yobume bendawo, eyentlalo-qoqosho nezenzo zokondla iintsana zoomama kuMasipala waseBuffalo, isithili se-Amathola

Ubume nomhla: UBume 0.0, Okuthowuba 2010

Inombolo yophunyezo lwentsulungeko: N10/02/025

Le fomu yemvume icacisayo inamacandelo amabini:

Uxwebhu lolwazi, apho sabelana ngolwazi kunye nawe.

Isiqinisekiso semvume, apho utyikitya ukuba uyavuma ukuthabatha inxaxheba.

ICandelo 1 Uxwebhu lolwazi

Intshayelelo

Nksz Obekekileyo……., Igama lam ngu ……..

Esi sifundo yinxalenye yophando lukaPatience Moloi olumkhokelela kwizifundo zakhe

zeeMaster's ekoNgeni. Ufunda kwiDyunivesithi yaseStellenbosch kwaye kungokunje wenza uphando malunga nemvume ecingisisiweyo: Izinto eziyezaxoxwa nezingakhange zicaciswe kakuhle kwizifundo ezenziwa KwiziBedlela zalapha e Monti.

Ndingathanda ukwabelana nawe ngolwazi oluthile kwaye ndikumeme ukuba uthabathe inxaxheba kwesi sifundo sophando. Phambi kokuba ugqibe ukuthabatha inxaxheba ungathetha naye nabani na oziva ukhululekile kuye malunga nophando, kuquka usapho lwakho ukuba unqwenela ukwenza njalo. Kungakho amagama kule fomu ongawaqondiyo. Nceda ndicele ukuba ndime njengoko siqhuba nolwazi kwaye ndiza kuthabatha ixesha ukucacisa. Ukuba unemibuzo emva kwexesha, ungayibuza kum okanye elinye ilungu elikwiqela lophando.

INjongo

Injongo zoluphando kukuhlola ukuqonda kwakho malunga nemvume ecingisisiweyo ngexesha ubuthatha inxaxheba kwisifundo nakunye naluphi na uphando.Sinoloyiko lokuba abathathi nxaxheba bangenzeka ukuba ngamanye amxesha abakuqondanga ncam obekucacisiwe sinethemba oluphando

Uhlobo longenelelo

Olu luphando kwaye siza kuqhuba udliwanondlebe kunye nawe oluza kuthabatha imizuzu engama- 30. Ukuba uyavuma ukuthabatha inxaxheba kwesi sifundo indima yakho iza kukuphendula imibuzo kwiphepha lemibuzo malunga nesivumelwano esicingisisiweyo obusinikile kuphando obuthathe inxaxheba kulo.

Uchongo lwabathabathi-nxaxheba, uMgaqo noMgaqo ongenakwaphulwa

Inani labantu liza ngamakhosikazi athabathe inxaxheba kwizifundo eziphandwa lisebe le Effective Care Research Unit(ECRU).Uye wamenywa ukuba uthathe inxaxheba koluphando lwemvume icingisisiweyo ngoba ubuye watyikitya iphepha mvume uvuma ukuthatha inxaxheba kwesinye isifundi esiqhutywa ngu(ECRU).Ukuba uyavuma ukuthatha inxaxheba kwesisifundo umphandi uzakukubuza imibuzo embalwa ,impendulo zakho zizakubhalwa kwipahepha eliqokelela incukacha ,okanye ukuba uyakwazi ukufunda ubhale sicele uzibhalele ngokwakho .

Imigaqo engaqhelekanga

Akukho migaqo ingaqhelakanga iza kwenziwa ngaphandle kokubuza imibuzo ethile.

Ixesha elisikiweyo

Uqokelelo lolwazi luza kuba lixesha lemizuzu eyi 30.Lona oluphando luzakuqhuba kude kuphele inyanga ka Novemba 2009.

IMingcipheko nokungaZinzi

Akukho mingcipheko ibandakanyekayo ekuthabatheni inxaxheba kwesi sifundo. Akukho kungazinzi kucingelekayo kwesi sifundo.

IiNzuzo

Akukho nzuzo ithe ngqo iza kuwe kodwa intathonxaxheba yakho inganakho ukusinceda ukuba sifumane impendulo kumbuzo wophando njengoko kucacisiwe ngentla apha. Kungangabikho nzuzo ngeli nqanaba lophando, kodwa iziphumo zolu phando zingasinceda ukuba sifumane ukuba zikhona na iindlela ezinokunceda oomama kwixa elizayo baqonde kakuhle xana benikezela imvume ecingisisiweyo.

I-inshorensi

Ukuqhutywa kolu phando kuza kuhambelana neZindululo zoMbutho woNyango weHlabathi oKhokela ooSonzululwazi kuPhando lwezoNyango lweBhayoloji oluQuka iZifundo zoLuntu, isibhengezo sikaHelsinki nezikhokelo ezilungileyo zezenzo zonyango

IMfihlo

Kungenzeka ukuba abanye kuluntu bazi ukuba uthabatha inxaxheba kolu phando, bangakubuza imibuzo. Asizi kwabelana namntu ngabo bathabatha inxaxheba kolu phando. Ulwazi esiluqokelela kolu phando luza kugcinwa luyimfihlo. Ulwazi olumalunga nawe oluza kuqokelelwa ngexesha lophando aluzi kwaziswa ngegama lakho. Amaphepha emibuzo aza kugcinwa khuselekileyo kwaye negama lakho kuphela liza kuba kwifomu yemvume. Kuza kubakho inombolo yokwazisa kwiphepha lemibuzo ukunxulumana nemvume ecacisayo kunye nephepha lemibuzo. Oku kwenzelwa iinjongo zophando kuphela. Akukho lwazi lufunyenwe kuwe kuza kwabelwana ngalo okanye lunikwe omnye umntu ngaphandle kweqela lezophando.

UKwabelana ngeZiphumo

Ulwazi esilufumana ngokwenza olu phando kuza kwabelwana ngalo nawe phambi kokuba lwenziwe lufumaneke kuluntu. Siza kubeka izaziso ekliniki zokuba iziphumo ziyafumaneka kwaye nalapho unokuzifumana khona iziphumo. Ukongeza apho kuza kubakho iintlanganiso kuluntu ukwabelana ngeziphumo zophando. Iziphumo kwakhona ziza kupapashwa kwiincwadana zezifundiswa ukuze abanye abantu abanomdla bafunde kolu phando lwethu

Intathonxaxheba yokuzitahndela neLungelo loKwala okanye ukuRhoxa

Intathonxaxheba yakho kolu phando ngokupheleleyo yeyokuzithandela. Ungazikhethela

ukuba uthabatha inxaxheba okanye hayi. Ukuba ukhetha ukuthabatha inxaxheba okanye hayi, zonke iinkonzo ozifumanayo kule kliniki ziza kuqhuba kwaye akuzi kubakho tshintsho. Ungayitshintsha ingqondo yakho emva kwexesha kwaye uyeke ukuthabatha inxaxheba nkqu nokuba ubusele uvumile ngaphambili ukuthabatha inxaxheba. Kukuwe ukuba uthabathe inxaxheba okanye hayi kwaye onke amalungelo akho aza kuhlala ehlonitshiwe.

Okunye onokukwenza endaweni yokuThabatha inxaxheba

Ungakhetha ukungathabathi nxaxheba kolu fundo kodwa loo nto ayizi kukuchaphazela nangayiphi na indlela kuba olu luphando nje.

Imvume yensulungeko

Esi siphakamiso siqwalaselwe kwakhona saza saphunyezwa yiKomiti yeNtsulungeko yeSineythi yeDyunivesithi yaseStellenbosch, kananjalo nekomiti yeNtsulungeko yeMonti eliMbaxa. Injongo yezi komiti kukuqinisekisa ukuba abathabathi-nxaxheba bophando bayakhuseleka. Ukuba unqwenela ukufumana ngakumbi malunga ne-IRB, qhagamshelana noMandisa Singata, ECRU, iSibhedlele iCecelia Makiwane, 082 420 1743).

Ngubani onkuQhagamshelana naye

UNksz emsebenzini Ms Patience Moloi 043 708 2120, ekhaya 043 708 2441, okanye: i-imeyile: pmoloi5@gmail.com

Okanye naye nowuphina umsebenzi ongumphandi weEffective Care Research Unit (Umongikazi Okanye u Gqirha)

Ungaqhagamshelana nabo ngalo naliphi na ixesha unemibuzo enxulumene nolu phando.

Phambi kokuba ndikucele ukuba utyikitye le fomu yemvume, ndingakucela ukuba undicacisele ngamaziw akho ngothe wakufunda kutshanje okanye le nto ndigqiba kukucacisela yona. Ndifuna ukuqinisekisa ukuba uyaqonda ukuba uyavuma ukuthabatha inxaxheba kolu phando.

ICANDELO II: ISiqinisekiso seMvume

Ndimenyiwe ukuba ndithabathe inxaxheba kuphando lokuhlola ukuqonda kwakho malunga nemvume ecingisisiweyo ngexesha ubuthatha inxaxheba kwisifundo nakunye naluphi na uphando.Sinoloyiko lokuba abathathi nxaxheba bangenzeka ukuba ngamanye amxesha abakuqondanga ncam obekucacisiwe sinethemba oluphando Ndiyaqonda ukuba akukho mingcipheko ebandakanyekayo kwaye ndiyazi ukuba akuzi kubakho nzuzo eza kum siqu kwaye andizi kubuyekezwa ngaphandle kweendleko zehambo. Ndilinikiwe igama lomphandi onokuqhagamsheleka lula ngokusebenzisa inombolo nedilesi endiyinikiweyo yala mntu

Ndilufundile olu lwazi luqhubayo, okanye ndilufundelwe. Ndibe nalo ithuba lokubuza imibuzo malunga nalo kwaye nayiphi na imibuzo endiyibuzileyo iphendulwe ndaza ndeneliseka. Ndiyavuma ngokuzithandela ukuthabatha inxaxheba njengomthabathi-nxaheba kolu phando kwaye ndiyaqonda ukuba ndinalo iIungelo lokurhoxa kolu phando ngalo naliphi na ixesha ngaphandle kokuba kuchaphazeleke inkathalelo yezempilo yam neyosana lwam yexa elizayo.

Bhala Phantsi iGama loMathabathi-nxaxheba_____

UMtyikityo woMathabathi-nxaxheba _____

UMhla _____ USuku/inyanga/unyaka

Bhala Phantsi iGama loMphandi_____

UMtyikityo woMphandi _____

UMhla _____ USuku/inyanga/unyaka

Ukuba akukwazi kufunda nokubhala gcwalisa noku kananjalo:

Ingqina elingakwaziyo ukufunda nokubhala malityikitye (ukuba kuyakwazeka, lo mntu kufuneka achongwe ngumthabathi-nxaxheba kwaye akufuneki abe uyazana neqela lophando).

Ndikubonile ukuchaneka kokufunda kwefomu yemvume esuka kumthabathi-nxaxheba onokubandakanyeka, kwaye nalo mntu ulifumene ithuba lokubuza imibuzo. Ndiyangqina ukuba lo mntu undinike imvume ngokukhululekileyo.

Bhala phantsi igama lengqina_____ KUNYE

Nobhontsi oshicilelweyo womthabathi-nxaxheba

Umhla _____ USuku/inyanga/unyaka

Umtyikityo wengqina _____

Umhla _____ USuku/inyanga/unyaka

Ndifunde ngokuchanekileyo okanye ndibone ukuchaneka ufundo lwefomu yemvume

esuka kumthabathi-nxaxheba onokubandakanyeka, kwaye nalo mntu ulifumene ithuba lokubuza imibuzo. Ndiyangqina ukuba lo mntu undinike imvume ngokukhululekileyo.

Bhala phantsi igama loMphandi_____

Umtyikityo woMphandi _____

Umhla _____ USuku/inyanga/unyaka

Ikopi eyiyo yale Fomu yeMvume inikezelwe kumthabathi-nxaxheba _____

Ikopi eyiyo yale Fomu yeMvume ithatyathwa isiwe ukuba ifayilishwe kwindawo ekhuselekileyo kwiyunithi yezophando _____ (Ifakwe amgama okuqala omphandi)

UNIVERSITEIT•STELLENBOSCH•UNIVERSITY
jou kennisvennoot • your knowledge partner

06 May 2010 **MAILED**

Ms GP Moloi
Division of Nursing
2nd Floor, Teaching Block
Faculty of Health Sciences
Tygerberg Campus
7505

Dear Ms Moloi

"Informed Consent: Communication and miscommunication in clinical trials"

ETHICS REFERENCE NO: N10/02/025

RE : APPROVAL

It is a pleasure to inform you that a review panel of the Health Research Ethics Committee has approved the above-mentioned project on 06 May 2010, including the ethical aspects involved, for a period of one year from this date.

This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project number in ALL future correspondence. You may start with the project. Notwithstanding this approval, the Committee can request that work on this project be halted temporarily in anticipation of more information that they might deem necessary.

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly and subjected to an external audit.

Translations of the consent document in the languages applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Please note that for research at primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Hélène Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

Effective Care Research Unit
EVIDENCE BASED HEALTH CARE FOR ALL
University of Fort Hare
Together in Excellence

Frere Hospital, Amalinda Drive, East London 5200. Tel/fax: (043) 709 2483. Email: mandisas@ecdoh.co.za
Cecilia Makiwane Hospital, Private Bag x13003, Cambridge 5207. Tel: (043) 708 2120; Fax: 043 7611158; Email: mandisa.shigabi@gmail.com

Stellenbosch University
Faculty of Health
Tygerberg Campus

To whom it may concern

RE: **Informed Consent: Communication and Miscommunication study permission**

Informed Consent: Communication and Miscommunication study is one of the studies that was carried out at the Effective Care Research Unit. Patience Moloi was given permission to conduct her study for her Master's Degree within our Unit.

Ethical approval was received from Stellenbosch University. This was enough to carry on and conduct her research as this was not a clinical trial.

Yours Truly,