CHAPTER 4

ETHICAL CLEARANCE FOR RESEARCH IN THE HEALTH SECTOR

4.1 Introduction

In this chapter a scrutiny is made of ethical clearance for research in the health sector. What influences ethical clearance, the length of time taken for ethical clearance on a project's outcome are scrutinised. The path's that were taken, specifically by RN4CAST, to obtain ethical clearance for research in the health sector are also examined.

Ethical clearance in the health sector can be quite time consuming. It can also affect the outcomes of a project. For example: a recipient receives money to carry out a project (specifically in the health sector) over a period of three years, it takes the recipient one year to get ethical clearance for the research. That means that there are only two years left of the project's initial three years, because a project cannot begin before ethical clearance is obtained, thus shortening the project by one third of its planned time period.

4.2 Background to Ethical Clearance

During World War II some people who were classified as inconsequential were subject to inhumane medical research, as the Nazi's only concern was their own wellbeing. The Nazi's mostly used prisoners from concentration camps for their experiments, exposing them to excruciating pain, to gain medical information. According to "Wartime Experiments on the Inmates of Nazi Concentration camps" (2011), one of these people was Dr Josef Mengele, also known as the "Angel of death". Most of these doctors lost sight of their moral principles when conducting these inhumane and unlawful practices on human beings. After World War II most of these doctors were brought to justice before the International Military Tribunal at Nuremburg. Here twenty doctors were found guilty of war crimes and crimes against humanity. Incredibly Dr Josef Mengele wasn't among the doctors found guilty.

After World War II a need for a code of ethical conduct was recognised. Following the Nuremburg Tribunal, the Nuremburg ethical code was formulated. American judges formulated this code in 1949 to protect humans against unethical and inhumane treatment.

It is however, surprising that a World War was needed in order to formulate a code of ethical conduct, as moral and ethical conduct is firmly established in religion and philosophy. The general principle of ethical conduct is known in philosophy as the "Golden Rule."

The golden rule (as known by philosophy) is: "Do as you would be done by." This principle has for centuries been accepted as the guiding principle of conduct. In 500BC, Confucius said: "What you do not wish for yourself, do not do to others. As you yourself desire standing, then help others achieve it; as you yourself desire success, then help others attain it." In the New Testament we find Jesus advocating the Golden Rule when He commanded: "So in everything, do unto others as you would have them do unto you, for this sums up the law and the prophets." (Holy Bible)

Unfortunately the cruelties of war, resulting from human weakness and misdemeanour, necessitated more specific rules of conduct. A general principle of moral conduct, such as the Golden Rule, often seems to be laid aside.

4.2.1 Nuremberg Code (1949)

The Nuremberg Code of 1949, also known as the Universal Code of Research Ethics, had as its objective the establishment of an ethical code of conduct for guiding humans.

The American judges defined ten research principles necessary for conducting medical research on human beings, thus ensuring the protection of human rights for participants in all experiments. Among these principles was the need for consent from the participant prior to any research, and the right to withdraw at any time during or prior to any experiments concerning research in the health sector. Participants must also be protected from any physical and mental suffering, injury, disability or even death caused by these experiments.

Furthermore the Nuremburg Code states that the benefits and risks of the study's/experiments must be weighed against each other, to ensure a balance is reached between the two (Wartime Experiments on the Inmates of Nazi Concentration camps, 2011).

4.2.2 Declaration of Helsinki (1964)

The International code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care, which might have the effect of weakening the physical and medical condition of the patient." It also stated that the progress of research depends on the way humans react to experiments. Because unethical research was continued the World Medical Association (WMA) adopted the Declaration of Helsinki in 1964. The aim of this was to provide guidance to physicians and others involved in research on human subjects (World Medical Association Declaration of Helsinki, 1964).

The Declaration of Helsinki has been reviewed six times, in 1975, 1983, 1989, 1996, 2000 and lastly in 2008. The only valid version is the 2007-2008 declaration. These are only guidelines to physicians across the world. The Declaration of Helsinki comprises guidelines differentiating between therapeutic and non-therapeutic research. These guidelines can be summed up accordingly:

It is the duty of the physician involved in medical research to protect the life, health, privacy and dignity of persons involved as experimental subjects. The experiments must also be conducted scientifically but successfully on animals first. The persons conducting the research must be scientifically qualified. The participant must be fully informed of all procedures he/she has to undergo as well as the consequences of the procedures or medication taken. Lastly all published research must be accurate.

4.2.3 Belmont Report (1978)

Health science research, from the National Institutes of health (2011), indicated that the Declaration of Helsinki was inadequate. Therefore, the American Government commissioned an investigation into these guidelines, to resolve the issue of protecting human subjects in research.

The National Commission for protection of Human Subjects of Biomedical and Behavioural Research (USA) was established in 1978 and compiled the Belmont Report in the same year. The Belmont Report aims to ensure research is conducted ethically on human subjects.

The Belmont Report consists of three principles relevant to research done involving human beings. These principles are:

1. Respect for persons, this includes a person's autonomy.
2. Beneficence – meaning that one should do no harm and minimise any harm as far as possible.
3. Justice – meaning that all people should be treated fairly.

According to the National Institute of Health, the Belmont Report can be summarised as "a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects".

The Nuremburg Code (1949), The Declaration of Helsinki (2007-2008) and the Belmont Report (1973) are internationally recognised for Health Research Ethics (HRE). They were also used to form the National Health Research Ethics Council's Guidelines, which was developed by the Department of Health (DoH) of each country. This must also be adhered to when research is conducted in a particular country.

4.2.4 Universal Declaration of Human Rights of 1948

The Universal Declaration of Human Rights was ratified in 1948, even before the Nuremburg Code (1949) was ratified. This declaration was developed as guidelines on how human beings should treat each other. It states that: every human being is born free and should treat others with dignity and respect; every human being is entitled to be treated equal; there is no gender or race discrimination, amongst other discriminations. Member states have pledged themselves to achieve these declarations in co-operation with the United Nations.

The Universal Declaration of Human Rights was proclaimed by the General Assembly of the United Nations and applies to all peoples of all nations.

The Universal Declaration of Human Rights states that every human being must be recognised with equal and inalienable rights to freedom, justice and peace.

The "Nuremburg Code", "The Declaration of Helsinki" and "The Belmont Report" are recognised internationally. Most countries have them enshrined into their national health guidelines and health laws, made by their respective Departments of Health. The "International Dimension to Research Ethics, the Significance of International and other non-UK frameworks for UK social science" (2011), includes a number of guidelines that establish ethical and scientific standards internationally. Some of them are:

- ICH guidelines for Good Clinical Practice (GCP) by the World Medical Association (WMA) (WMA 2000, ICH 1996).
- Council for International Organizations of Medical Sciences (CIOMS); International Ethical Guidelines for Biomedical research involving human subjects (CIOMS 2003).
- ESRC Research Ethics Framework.
- WHO Guidelines (WHO 2000).

The following are international ethics committees: WHO, (ICH) and the International Health Research Council (IHRC).

The above guidelines apply to most human subjects' research funded by the federal government of a country or regulated by the FDA anywhere in the world. Until recently, most ethical reviews of international research took place in the developed country institutions doing the sponsoring.

Since World War II, many ethics standards have been adopted on a national basis in Europe. In recent years there has been a tendency to replace the mainly independent handling of research ethics by professional bodies with legal acts (such as acts regulating embryo, stem cells and genetic research) and internationally recognised guidelines that are accorded semi-legal status. (The International Dimension to Research Ethics: the Significance of International and other non-UK Frameworks for UK Social Science, 2011).

When one collaborates internationally, it is essential to adhere to these international guidelines. More and more international collaboration is taking place, thus emphasising the necessity of knowing these guidelines.

Along with other countries, South Africa also has a constitution (Constitution of South Africa, Act 108 of 1996). The Bill of Rights is a fundamental part of the constitution, and also applies to research in the health sector.

4.2.5 Bill of Rights (Act 108 of 1996)

The Bill of Rights, as described by the South African Government, is a cornerstone of South Africa's democracy. All the people's rights are enshrined in it. This includes the democratic values of human dignity, equality and freedom. It also states that everyone is entitled to life, thus everyone has the right to have access to health care, education and sanitation.

The Nuremburg Code, The Declaration of Helsinki and the Belmont Report all influenced ethical codes for research in South Africa. The National Health Act contains one such guideline.

4.2.6 National Health Act (Act 61 of 2003)

According to the Government Gazette, the National Health Act was issued "to provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith."

The above codes also helped formulate the Ethics in Health Research: Principles, Structures and Processes (DoH, 2004), which was developed in 2004 as a guideline.

4.2.7 Ethics in Health Research: Principles, Structures and Processes

These guidelines were formed uniquely for South Africa's national needs and are also national policy on ethical practice of research. In these guidelines sound ethical considerations for a research proposal are viewed as equally important as scientific considerations (DoH, 2004:1-2). Directed by the guidelines a review committee was also formed to oversee health research, with regard to ethical and scientific rigour (DoH, 2004:2).

This review committee, the National Health Research Ethics Council (NHREC) was formed as stipulated in the National Health Act.

4.2.8 National Health Research Ethics Council (NHREC)

The NHREC was established by the National Health Act as a guideline for GCP as well as the professional ethics codes to follow. According to DoH (2004:1-2), the NHREC are responsible for promoting South Africa's ethics compliance to legislation and regulation. They are also responsible for ethical standards and guidelines. The Minister of Health appoints fifteen members to form the NHREC. This council meets quarterly to advise the Minister of Health about health policy, whereas the secretariat of the DoH supports the NHREC by keeping a database of health research activities. In return the secretariat of the DoH appoints inspectors to monitor the functions of the NHREC (DoH, 2004:31).

4.2.9 Research Ethics Committees (REC's) in South Africa

The NHREC didn't replace ethics committees. All REC's in South Africa are required to be registered, audited and accredited by the NHREC (DoH, 2004:11). NHREC accreditation was developed using the South African Guidelines for Medical Research, as well as from other guidelines that are internationally recognised. REC's were divided into two levels by the NHREC, giving Level 1 REC's the authority to only review research proposals with a research budget of less than R250 000 and with minimal risk to participants. Level 2 REC's may review any type of research proposal.

Each province has its own Research Ethics Committee (PHREC) which uses the seventeen guiding principles that were formulated as part of the Ethics Health Research Guidelines (2004), to assist health researchers in their research. These guidelines ensure acceptable and desirable conduct, the protection of research participants' rights and welfare. The guidelines indicate the basic ethics considerations of justice, respect for all and beneficence (DoH, 2004:3-8).

Figure 4.1 below shows the NHREC's structure and activities in South Africa in short.

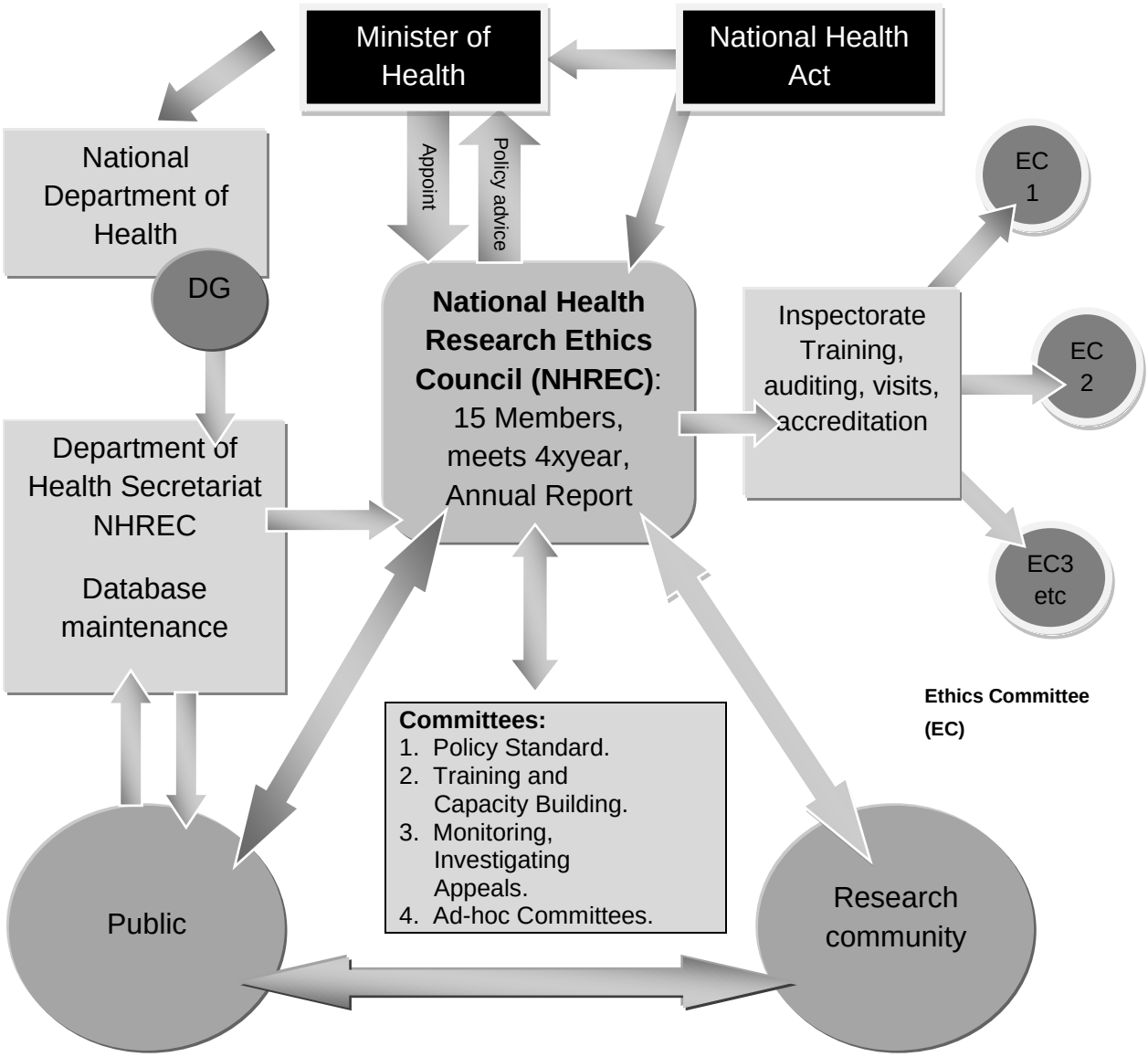

Figure 4.1: NHREC Graphic Depiction

Source: adapted from DoH, 2004:31

An investigation was made on how RN4CAST obtained ethical clearance for research they conducted about the health sector.

4.3 The Path of Ethical Clearance for RN4CAST

4.3.1 Background on RN4CAST Project

Leadership and policy development: improving the quality of nursing in South Africa through nurse staffing and patient safety (RN4CAST), with Prof HC Klopper as the principal investigator of this research programme. The investigation was conducted under the auspices of the North West University's School of Nursing Sciences, Potchefstroom. This project was also part of an international collaboration, which aims to develop human resource forecasting models in nursing (Sermeus, Iken, De Geest, Diomidous, Durna, Ekman, Klopper, Liu, Matthews, Morena-Casbas, Rafferty, Scott, Schoonhoven, Schubert, Shaibu, Tihelman, Anttypas, Brzostek, Bommels, Busse, Clarke, Delaure, Frigas, Griffits, Gustavsson, Kinnune, Liaskos, Lesaffre, Mantas, Van Achterberg, Van Den Heede, Wörz & Zikos, 2008).

RN4CAST's main aim was to conduct data collection in the private and public hospitals in six provinces in South Africa and to provide information that can be used to develop nurse forecasting models. The RN4CAST programme focuses on leadership and policy development and how this can improve the quality of nursing in South Africa through nurse staffing and patient safety.

4.3.2 Ethical Clearance obtained for RN4CAST

The RN4CAST project took approximately six months from submission to obtain ethical clearance. Ethical clearance had to be obtained on national, provincial and hospital levels. Ethical clearance was therefore obtained from the National Health research Ethics Committee (NHREC) and then from the Provincial Research Ethics Committee (PREC). Thereafter clearance was obtained from the University which conducted the project, in this case, the North West University. Lastly ethical clearance had to be obtained from the facility data was collected from, in this case the public and private hospitals.

Data was collected from six different provinces and in each province the procedure had to be followed from provincial level to hospital level. Obtaining ethical clearance was complicated as data was collected in six different provinces.

The process of obtaining ethical clearance for RN4CAST on all different levels is illustrated below.

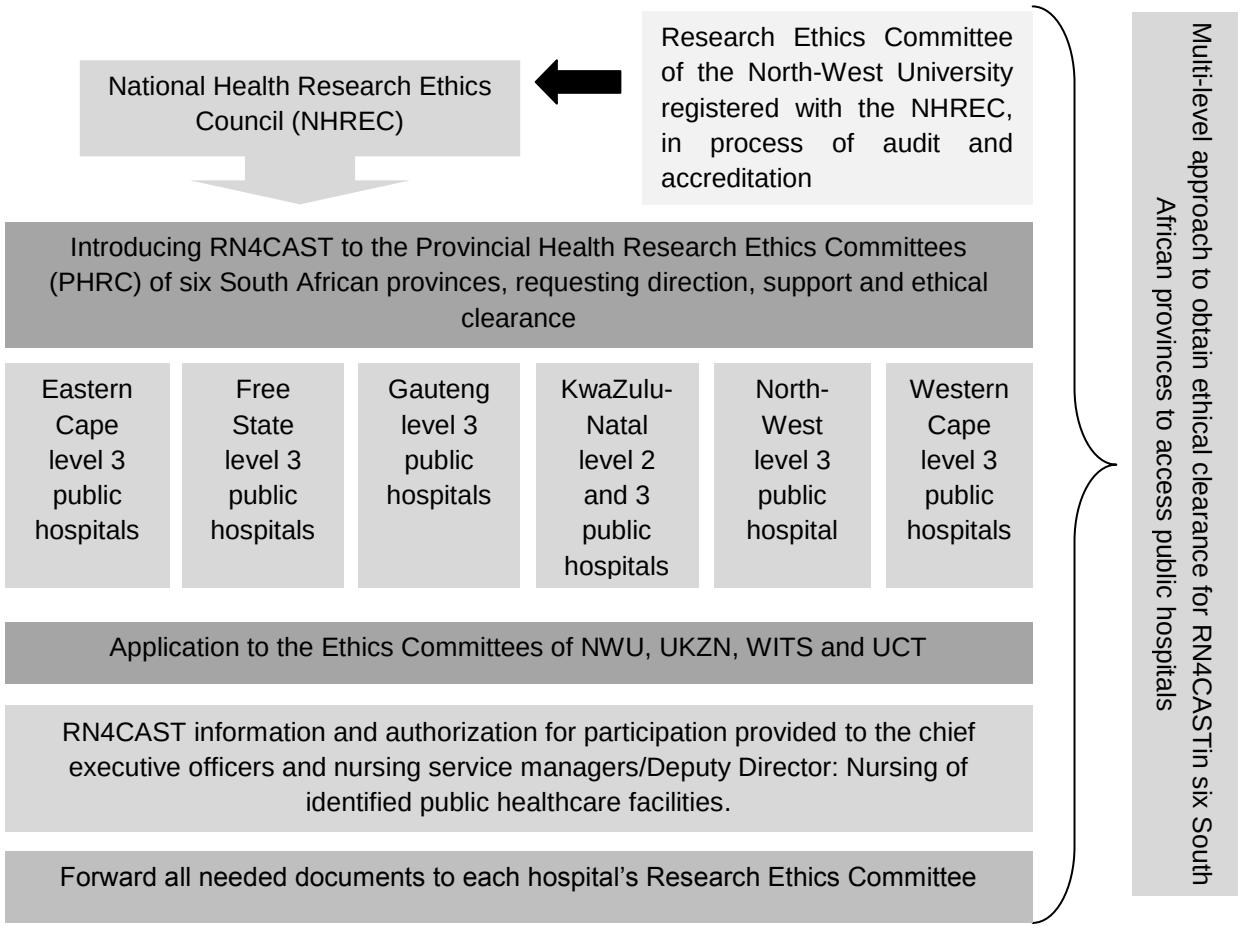

Figure 4.2: The Path of Ethical Clearance RN4CAST followed

Source: BESTER, 2011. Pearls and pitfalls in the ethic application for a national research programme in South Africa. (Unpublished Manuscript)

Research should never undermine existing services, but rather improve them.

- Emanual et al. 2004:933

As illustrated above, the path taken by RN4CAST was complicated as ethical clearance was requested from each of the six provinces. Each province had to obtain ethical clearance from their particular Provincial Health Research Ethics Committee (PHREC), as well as from the Human Research Ethics Committee (HREC) of each University (NWU, UKZN, WITS, and UCT) and lastly from the hospital the data was collected from. Public and private hospitals were separately approached.

The above can be summarised in the figure below.

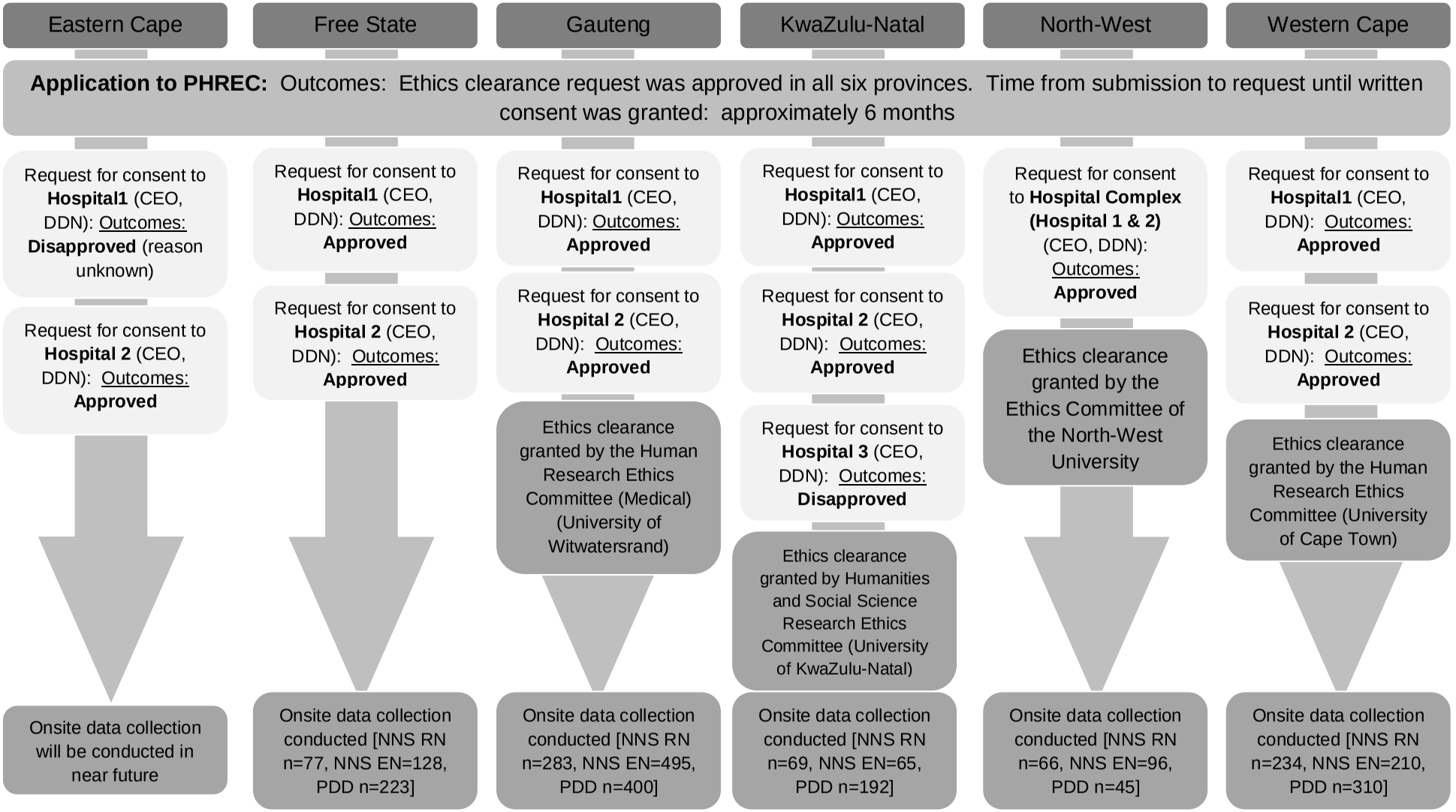

Figure 4.3: Extent of Ethics Clearance and Consent to Conduct Research and Access Patient's Records.(CEO = Chief Executive Officer of the hospital; DDN = Deputy Director: Nursing; NNS RN = National Nurse Survey Registered Nurses; NNS EN = National Nurse Survey Subcategory Nurses; PDD = Patient Discharge Data survey)

Source: BESTER, .2011. Pearls and pitfalls in the ethic application for a national research programme in South Africa. (Unpublished manuscript).

As mentioned above, the time it took to obtain ethical clearance before any data could be collected at any hospitals, was approximately six months. The timeframe in which the RN4CAST project needed to be completed was two years, thus the project "lost" a quarter of its total project lifecycle, whilst waiting for ethical clearance. This had a profound influence on the outcome of the project, as the "lost" time could have been spent on essential aspects of the project.

4.4 Time versus Cost

Obtaining ethical clearance can be costly, not only because of the delay of the project, but also because of the process that needs to be followed to obtain ethical clearance. Travelling to the different provinces in South Africa needs to be done, or the necessary papers need to be sent by courier to the appropriate participating parties.

4.5 Effectiveness of Reaching Original Goals

A project in the health sector is not allowed to continue before ethical clearance has been obtained. Thus the project comes to a complete halt while waiting for ethical clearance. The effect on the outcome of a project can be overwhelming, as 10% (six months of a five year project) - 25% (six months of a two year project) just disappears, depending on the duration of the project. Initial goals are not attained with the same effectiveness as if time wasn't lost.

4.6 Chapter Summary

All research projects in the health sector require ethical clearance before the appropriate research can begin. Most donors are unaware of the processes required to obtain ethical clearance, especially if the donor is from another country and not familiar with the recipient countries ethical processes.

In this chapter the significance of obtaining ethical clearance for projects was emphasised. Project funds should be applied in an ethical justifiable manner. It is not only morally correct, but when a project is funded with donor funds, the donor will also require proper utilisation of their funds. When using donor funds in the health care industry, ethical application becomes imperative. Ethical clearance does affect the outcome of a project,

due to the financial and time restraints.The project comes to a halt when waiting for ethical clearance. The RN4CAST Project discussed in this chapter was delayed by six months – a quarter of the duration of the two year project.

During this period of waiting for ethical clearance a personnel member needs to be employed to oversee this process. Obtaining ethical clearance is also costly, in the case of NR4CAST the cost implication, obtaining ethical clearance and the remuneration of the personnel member for this time period amounted to ten per cent of the total funding received. If ethical clearance is not obtained, the project cannot continue and the donor will withdraw funding. In most cases personnel with the required expertise are employed to work on the project. If ethical clearance is not obtained the company/institution would lose the ten per cent and be compelled to cover the costs themselves. In the case of RN4CAST the funding was paid over only after the ethical clearance certificate was sent to the donors and initial costs had to be paid out of the companies/institutions own pocket until funds were received.

If projects do not reach the desirable outcome, donors may decide to withdraw funding to other projects in the same company/institution, which may lead to great financial losses. Thus it is crucial for recipients to know the processes (as well as duration) involved for obtaining ethical clearance, if they want to ensure the maximum outcome of their project, and reach initial goals in less time. Consequently planning the budget, and outlay of the project, may just make the necessary difference.