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Knowledge and Perception of Health Research Ethics among Health Care Professionals at Greys Hospital

Pietermaritzburg – South Africa

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in Health Research Ethics

By

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Supervisor: Prof G Lindegger **November 2016**

Declaration

I, Omran El-Koha, hereby declare that this is my original work and it has not been submitted to this or any other universities. All references and source materials that has been utilised in this dissertation, have been indicated and acknowledged.

This work was supervised by Prof. G Lindegger (Department of Psychology)

Omran El-koha

November 2016

Dedication

To my two little children

Mohamed and Yakeen

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Abstract

Objectives:

To explore familiarity and awareness of codes and regulations related to the conduct and practice of research ethics among health care professionals. Furthermore, to establish the level of knowledge of research ethics and relate that to research experience and level of training in research ethics

Methods and materials:

A survey based study of 20 self-administered questionnaires about reported and actual knowledge of research ethics was distributed to various categories of staff at Greys hospital using convenience sample. In total 152 questionnaires were distributed. The study was approved by the biomedical and research ethics committee (BREC) of UKZN. Data were collected and entered into SPSS (version 20). Data were analysed using frequencies, cross tabulations, Pearson's coefficient and one way analysis of variance (ANOVA).

Results: The completed questionnaires were returned by 103 participants with a total response rate of 67.7%. Doctors comprised 55% of all responses. Consultants, medical officers, and registrars formed 28.16%, 21.36%, 5.83% of the sample respectively. Nurses contributed 12.6% of all responses. 65.05% of the respondents were females, whereas 32.04% were males. Only 18% had full knowledge of informed consent. 68 % knew about research ethics committees, but the majority were not aware of its structure and function. Results clearly indicated an inadequate knowledge of ethics guidelines, and the majority of respondents had either little or very little knowledge on all the ethical codes and guidelines. Council for international organisations for medical sciences (CIOMS) appeared to be the least known and World Health Organisation (WHO) the most known of all guidelines. Twenty percent of respondents reported to have no research experience. Results also showed positive correlation between knowledge of ethics in general and training and research experience.

Conclusion:

The study concluded that the level of knowledge and awareness of research ethics among health care professionals at Greys hospital was generally poor. Therefore, improvements in research ethics education is recommended for health care professionals at all levels. Furthermore, larger studies are needed to confirm these findings.

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1 INTRODUCTION AND REVIEW OF LITERATURE

1.1. INTRODUCTION

Medical and health research is conducted with human participants and involves interventional, social and behavioural aspects. Research ethics seeks to protect human participants, encourage ethical research and ensure that the safety, dignity and the well-being of participants are sustained throughout the research process (National Institute of Health, 2013).

Research ethics is based on applying the ethical principles and guidelines pertinent to the design, conduct, analysis and reporting of social science and clinical studies. The four main principles which form the basis of research and medical ethics include autonomy, beneficence, non-maleficence, and justice (Beauchamp & Childress, 2001).

Evolution and improvements in research ethics has happened in light of an era of unethical research. Despite the development of international regulations and guidelines, incidents of unethical research and scientific misconduct are still reported, which might be attributed to a lack of training and guidance for researchers. This has led to an increased awareness and attention among health care professionals and regulatory authorities to conduct ethical research (Hariharan, Jonnalagadda, Walrond, & Moseley, 2006).

Appropriate training of health care practitioners is considered essential for ethical and legal conduct. Although it seems that medical and research ethics are incorporated in the curriculum of medical training in South Africa, only few health care professionals receive formal and structured medical or research ethics training after being qualified where they will be faced with ethical challenges in research (Walrond, Jonnalagadda, Hariharan, & Moseley, 2006).

There are many recommendations and strategies to improve the teaching of health decision making in clinical practice (Goldie, Schwartz, & Morrison, 2000; Sulmasy, Geller, Levine, & Faden, 1993) .

Justification of study

In order to formulate and frame research ethics training at Greys hospital, Pietermaritzburg, the initial step of this study was to assess the current knowledge and attitudes of the healthcare professionals concerned. This study was an attempt to evaluate the knowledge, attitude and practice of health care professionals regarding research ethics (Mohammad, Ahmad, Rahman, Gupta, & Salman, 2011). This study is one of the first to establish a baseline measure of research ethics knowledge amongst healthcare professionals in South Africa, which may lead to the development of better research ethics training in future.

Why Greys Hospital?

Greys hospital is a referral facility providing tertiary services to the large population of the North and North West areas of KwaZulu-Natal, and provides regional services to the local population. More than one thousand health care professionals are employed including medical and allied health care staff. The number and diversity of staff at Grey's has made this an ideal site for this study.

1.2. REVIEW OF LITERATURE

History and development of research ethics

The conduct of unethical research has a very long history dating back to the ancient and classical Greek era. Vaccine trials are an example of early unethical experiments during the 17th century (*National statement on ethical conduct in human research*, 2007).

There has been rising awareness amongst researchers and regulatory authorities on research ethics since the Second World War. The evolution and advancements of research ethics has occurred due to exploitation of human participants in early clinical and social research, which eventually led to the development of regulations and guidelines of research ethics (Hariharan et al., 2006). This section analyses the advancements and course of events of the historical evolutions of regulations and guidelines of human research ethics.

Historical events and abuse of human participants

17th – 19th century

In the 17th century the experiments of vaccine trials were carried out on human participants. Physicians tested vaccines on themselves and their families. During this time, Edward Jenner (1749 - 1823) administered the smallpox vaccine to his son and other neighbourhood children. Johann Jorge (1779 - 1856) experimented on his own body by swallowing 17 types of drugs in different doses to examine their pharmacological properties .(Sierra, 2011).

20th century

Yellow fever trials were conducted by Walter Reed on himself and other human participants. This experiment contributed significantly toward major advances in medicine.(Sierra, 2011).

Nuremberg –WWII (1939–1945)

During World War II, many medical experiments were conducted on human participants without consent. These human participants consisted mostly of concentration camp prisoners and Nazi German doctors performed these experiments. The prisoners of concentration camps were injected with gasoline and live viruses, immersed in ice water, and forced to ingest poisons. This resulted in significant harm and lead to the death of many of those prisoners. The Nuremberg trial led to 23 German doctors being criminally charged for human rights violations, and for corrupting medical science (National Institute of Health, 2013).

Tuskegee syphilis study (1930-1972)

The Tuskegee syphilis study was conducted between 1930 and 1972. The study aimed to investigate the effect and progression of untreated syphilis in African American men in Alabama (Clark et al., 2012). The health service of Alabama State and Tuskegee institute were the sites for this study. Approximately 600 human participants were recruited for the study without informed consent. There were 200 control participants and 400 participants that were infected with syphilis. Infected participants were not told about their infection and they were not treated for syphilis. Penicillin was discovered in the 1940s and was available for clinical use, however it was not used to treat the infected participants. In 1973, the government of United States compensated the participants and provided medical care for the survivors and their families. In 1997 president Bill Clinton made a public apology (Clark et al., 2012).

The Tuskegee trial outcome resulted in the death of many participants and syphilis infection of women from their partners and birth of syphilis infected children. This study violated all the basic principles of ethics, i.e. autonomy, beneficence, non-maleficence, and justice.

Willowbrook hepatitis study (1950s)

Mentally challenged children in New York were purposefully infected with the hepatitis virus. Although, parents' consent to enrol their children in the study, participants were not well informed about the risks. There were concerns regarding the ethical conduct of the study as participants were exposed to discrimination(Sierra, 2011).

The Wichita Jury Study (1953)

During a Wichita trial a research team recorded the confidential deliberations of the jury without permission. This study violated the code of conduct of the institution as the judge and lawyers were aware of the study but not the jurors (Sjoberg, 1967).

Thalidomide (1950s)

In the late 1950s the drug, Thalidomide, was approved in Europe as a sedative, however, in the United States of America the drug, although unapproved by the FDA, was used as an anti-nausea medication for pregnant women. Pregnant women were prescribed the drug without being informed of its FDA status or the potential side effects and many women did not consent to taking the drug. The drug caused many infants to be born with congenital deformities (National Institute of Health, 2013).

Jewish chronic disease trial (1960s)

In order to test the immune systems' response to cancer, chronically ill dementia patients were exposed to live liver cancer cells. Valid informed consent to participate in the study was not obtained (Guraya, London, & Guraya, 2014).

San Antonio Contraception Study (1970)

The San Antonio contraception study tested contraceptive pills using Mexican American women. Without consent, women who were initially receiving the experimental drug received the placebo for the second half of study leading to unplanned pregnancies in some women (Sierra, 2011).

Tearoom Trade Study 1970's

In this study, personal information regarding homosexual men and their behaviour was gathered without their consent. The study included men who used to meet in public places for homosexual practices. Vehicle number plates were recorded and more information obtained. No informed consent was obtained(Sierra, 2011).

Research ethics in the 20th century

In the past years, several studies of unethical research have been reported. This includes genetic research, cancer, and psychiatric research. Two recent examples of unethical research are presented below:

Death of a Normal Volunteer

On March 31, 1996, a 19-year-old Asian American student at the University of Rochester participated in a study and underwent a bronchoscopy for the harvesting of alveolar macrophages. The bronchoscopy was difficult and required numerous doses of topical lidocaine. The participant suffered cardiac arrest and died on April 2, 1996. The death was investigated and findings revealed that the protocol did not limit lidocaine doses, and further there was no documentation of the doses that were given. The investigation also found that the participant was not observed after the bronchoscopy, and that the concentrations of lidocaine were increased without IRB approval (Sierra, 2011).

Death in Gene Therapy Trial

In the fall of 1999, 18-year-old Jesse Gelsinger died while participating in a gene transfer trial. Jesse had a rare metabolic disorder, ornithine transcarbamylase deficiency syndrome (OTC) that was being controlled by medication and diet. Researchers were testing an innovative technique using adenovirus gene transfer. Soon after treatment Jesse Gelsinger went into multiple organ failure and subsequently died. This case gained media attention and cast a spot light on research with human participants. Serious concerns relating to conflict of interest, data safety monitoring, and informed consent, have made the Gelsinger case a contemporary illustration of continued doubts about the ethical integrity of research with human participants. Due to this case, deliberations on many controversial topics have been discussed at a national level. The outcome of the discussions is yet to be determined (Sierra, 2011).

Witwatersrand University – South Africa

In 1992 Prof Bezwoda and colleagues presented early results of a randomized clinical trial of high dose chemotherapy for metastatic and high risk breast cancer at the American society for clinical oncology (ASCO) annual meeting; results were published in 1995 and were the first evidence that high dose chemotherapy was beneficial in comparison to conventional chemotherapy. However, an audit by a team of researchers showed a major discrepancy between the recorded and reported data. Some of the ethical issues encountered in this trial were: no signed informed consent by participants in the trial; the trial was not approved by the University of Witwatersrand ethics committee; there was little evidence of randomization; the protocol was written nine years after the study was started; there were at least three possible treatment-related deaths among patients receiving high-dose chemotherapy; and although the paper claimed that there were none, 61 of 90 records could be found. This was considered one of the most serious cases of scientific misconduct in the 20th century, however it was cited 354 times by researchers (Bezwoda, Seymour, & Vorobiof, 1992; Erikson, 2001; Weiss et al., 2000).

Challenges of ethics in old research

Some of the ethical issues encountered in the old research during which there were no regulations and guidelines were enrolment of vulnerable participants such as children, prisoners and mentally challenged, lack of informed consent, inadequate information to participants, withholding available treatments, exposing participants to high risk, biased selection of participants, coercion and undue inducement, and violation of the rights of participants.

Development of codes and regulations

The exposure of human participants to the risks and harms of unethical research enforced the need for rules and regulations in order to guide researchers and protect human participants. It also emphasized the value of ethics committees to review proposed projects and their practical and legal implications (Guraya et al., 2014).

The most studied guidelines of health research ethics are listed and discussed below.

Nuremberg code 1947

In 1947 the Nuremberg code was established and this is considered the foundation of recent research ethics. It was developed as a consequence of the Nuremberg Nazi crime trials in 1946. Nuremberg code recognized informed consent as an essential requirement for all ethical research. It is comprised of 10 sections. However, the code does not have power of law and was only ever applied to non-therapeutic research at that time (National Institute of Health, 2013).

Statements of Nuremberg code:

“1. Voluntary consent of the human participant is essential.

2. The experiment must yield generalizable knowledge that could not be obtained in any other way and is not random and unnecessary in nature.

3. Animal experimentation should precede human experimentation.

4. All unnecessary physical and mental suffering and injury should be avoided.

5. No experiment should be conducted if there is reason to believe that death or disabling injury will occur.

6. The degree of risk to participants should never exceed the humanitarian importance of the problem.

7. Risks to the participants should be minimized through proper preparations.

8. Experiments should only be conducted by scientifically qualified investigators.

9. Participants should always be at liberty to withdraw from experiments.

10. Investigators must be ready to end the experiment at any stage if there is cause to believe that continuing the experiment is likely to result in injury, disability or death to the participant” (National Institute of Health, 2013).

Universal Declaration of Human Rights – UN 1948

On the 10th December 1948, the United Nations adopted this document which states in principle that human rights need to be preserved at an international level ("Universal Declaration of Human Rights ", 1948).

Declaration of Helsinki – World Medical Association 1964

The Declaration of Helsinki, published by the World Medical Association (WMA). The declaration emphasized informed consent as a core standard for any ethical research. It allows for surrogate consent in case of incompetent participants. Since then it has undergone multiple revisions. In the 1975 revision, it was stated that research protocols should be reviewed by independent research ethics committee (Guraya et al., 2014; National Institute of Health, 2013).

The Declaration of Helsinki is considered to be one of the most important documents for promoting ethical principles in research involving human participants. The last revision of the declaration was during the 64th WMA General Assembly, Fortaleza, Brazil, and October 2013.

USA National Research Act - 1974

This act was established by the Commission for the Protection of Human Subjects and regulates all research related to human participants. It is also known as the Federal Protections for Human Participant and was developed after the Tuskegee Syphilis Study.

The Belmont Report – 1979

This was established by the National Commission for the Protection of Human Subjects in biomedical and behavioural research. It was issued on 30 September 1978 and published by the Federal Register on 18 April 1979. The report identifies and summarizes three basic ethical principles and guidelines for research with human participants, namely: respect for persons, beneficence, and justice. It also characterizes three fundamental ethical principles involving human participants: respect for persons means protection of autonomy of participants in research and allowing for informed consent. “To respect autonomy is to give weight to the autonomous person’s considered opinions and choices while refraining from obstructing his or her actions” (Beauchamp, 2008).

Beneficence: which means "Do no harm" while maximizing benefits and minimizing risks to participants of human research. “Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term beneficence is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation" (Beauchamp, 2008).

Justice: fair treatment of individuals and groups with no exploitation and administered selection procedure. “Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects” (Beauchamp, 2008).

CIOMS guidelines – 1982, 1993, 2002

"The Council for International Organizations and Medical Sciences (CIOMS) was formed in 1949 jointly by the WHO and the United Nations Scientific and Cultural Organization (UNESCO)" (Macrae, 2007, p. 177). These guidelines were compiled by CIOMS in collaboration with the Joint united nations programme on HIV/AIDS (UNAIDS). There are 15 guidelines that address various matters pertaining to research with human participants. These include vulnerability, informed consent, women as research participants, ethics review committees and externally funded research. It allows developed countries to help and assist developing countries in conducting ethical research (Macrae, 2007).

ICH – GCP (USA, EU, Japan)–1996

The purposes of the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines are to protect the rights of human subjects participating in clinical trials and to ensure the scientific validity and credibility of the data collected in human clinical studies. The main principle in the guideline is that the rights, safety, and well-being of the trial participants are the most important considerations and should prevail over the interests of science and society. The guideline will have an important and beneficial impact on the clinical trials conducted in the three participating regions (the United States, Europe, and Japan) as well as many other regions throughout the world. (Dixon, 1999).

Operational Guidelines for Ethics Committee that review Biomedical Research – WHO 2000

To facilitate and regulate the review of research protocols by ethics review committees in all countries around the world the WHO developed guidelines for the requirements of ethics review committees (function, structure, membership, funding, monitoring). The WHO recommends that all reviews should ideally be based on all established international guidelines and regulations as well as the local practices (World Health Organization, 2000).

Becheer article

An article on "Ethics and Clinical Research" was published by Dr. H. Beecher, an anaesthesiologist from Harvard medical school in 1966. He described 22 cases of ethical matters and controversies produced by well-known researchers and published in reputable journals. He commented that "medicine is sound, and most progress is soundly attained, if unethical research is not prohibited it will do great harm to medicine". It was thought unethical research is not common, until publication of this article. This article has improved awareness of researchers, and made the public more aware about the conduct of ethics in clinical research. (National Institute of Health, 2013, Beecher, HK 1966. Ethics and Clinical Research. The New England Journal of Medicine 274(24):1354-1360.)

Institutional Review Boards/Research Ethics Committees

Historically, the necessity for guidelines and regulations to control human research only emerged following the Nuremberg trials after World War II (1945) which lead to the development of the Nuremberg code in 1948. With further expansion of clinical research, more guidelines were developed, e.g. declaration of Helsinki (1964), NIH, Belmont report and WHO-2000. The main objective of RECs is to protect the research participants from potential risk associated with research through local and international governing guidelines and laws.

The role of the research ethics committee includes: identifying and assessing potential risks and benefits of research and promoting the principles of respect, beneficence, and justice in health research. Research ethics committees are also tasked with reviewing and approving research protocols that involve human participants before commencement of any research, both in the medical and social science fields. REC protocol evaluation is largely concerned with ethical issues such as confidentiality, payment, informed consent, however, RECs may also review scientific content; organize and hold regular meetings to ensure continuous and regular monitoring of ongoing studies.

Members of ethics committees must have the capacity to assess and evaluate ethics and scientific content of the submitted research protocols (World Health Organization, 2010). An REC should be multi-disciplinary and have representative members with diverse backgrounds and experiences including racial, cultural, and professional aspects. RECs must include community members and reflect the demographics of the community population. Research ethics committees should be independent from financial, professional, institutional, and political influences. RECs should be established in accordance of the regulations of the local country and the community they serve.

The main function of RECs is to review research projects and their supporting documents. RECs function as an authority to make decisions regarding approving, requesting modifications, or disapproving submitted research protocols. The REC mainly considers the following objectives when reviewing protocols: scientific validity trial design, recruitment procedure, confidentiality, informed consent, and community engagement.

According to the US department of health (2009) an “REC shall conduct periodic review of research at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research”.

A full review is required for research protocols involving higher risk, and the majority of members need to be present at these meeting where protocol is approved by voting of majority of the quorum.

An investigation or research project can only start after being approved by an REC. Monitoring is continuous management or surveillance to ensure that research participants are and will be adequately protected while research is being conducted. Monitoring of research is also the responsibility of other stakeholders, such as sponsors and other authorities. “Monitoring is a method of evaluating whether or not an approved research proposal was actually implemented according to the written research proposal and approval criteria of the REC, with no deviations” (Musesengwa, 2014, p. 44).

RECs face several challenges and difficulties, particularly in developing countries, these may include:

- Lack of funding and financial support to ensure effective operation of RECs.
- Lack of adequate knowledge of ethical guidelines and regulations. REC Members should receive training in local and international ethical and legal standards.
- Lack of resources and institutional capacity such as equipment, staffing.

Informed consent: the process and challenges

Informed consent is one of the most important and critical aspects of conducting ethical clinical research. It is increasingly recognized and considered as the foundation of clinical research and medical practice.

Informed consent can be defined as “the voluntary and revocable agreement of a competent individual to participate in a therapeutic or research procedure, based on an adequate understanding of its nature, purpose and implications” (Sim, 1986, p. 584).

Informed consent was first described as part of Nuremberg code in 1947 and is recognized as the foundation of recent research ethics. It clearly stated that "the voluntary consent of the human subject is absolutely essential" ("The Nuremberg Code," 1949, p. 1). In 1964 the world medical association developed the declaration of Helsinki which further emphasized informed consent as the corner stone for ethical medical research (National Institute of Health, 2013).

The 2000 revised version of Declaration of Helsinki indicated that each potential participant of clinical research must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal (World Medical Association, 2009).

For informed consent to be valid the research participant must be informed and competent and they must confirm that they understand and volunteer their participation. To ensure that participants are informed, it requires disclosure of the nature, purpose, methods, risks, benefits, harms of the research and alternatives available. Competency or capacity refers to the participants' ability to effectively make the decision to participate after understanding the information provided. Individuals who do not understand, are mentally or physically incapable or are considered minors cannot give consent without a power of attorney or legal guardian. Understanding is the participants' ability to understand the information given, this also refers to language barriers and verbal/written comprehension. Voluntariness refers to the participants' autonomy and decision to participate without the influence of coercion (Bhatt, 2015; Chima, 2013).

According to Bhatt, informed consent is much more difficult to obtain in developing as compared to developed countries. This can be attributed to several factors such as, the lack of education, healthcare resources and possible language barriers that inhibit adequate comprehension of the information. Some of the reasons for refusal to participate in clinical trials include, individuals who do not want to be admitted to hospital, they do not want to undergo multiple blood collections, do not want to comply with the study procedure and they do not like the potential risks.

Risks however only influence the decision of approximately 4% of participants which suggests that perhaps the other participants did not understand the information given or the quality of the informed consent process is lacking. Participants in developing countries were less knowledgeable of the voluntariness of clinical trials and were often concerned with the consequences of withdrawal or refusal of participation. Participants from developing countries were concerned with a decrease in medical care if they withdrew or refused participation (Bhatt, 2015; Mansour et al., 2015)

In the study conducted by Chadha and Repanos, results showed that medical staff does not completely understand informed consent, although it is regularly practiced. It is imperative that healthcare professionals to understand and adhere to the rules and guidelines of obtaining valid informed consent from participants in clinical research; However standardization of the informed consent knowledge and guidelines would greatly improve the process (Chadha & Repanos, 2004).

In the conduct of ideal informed consent; all principles should be adhered to and should be included in a conversation initiated by the healthcare practitioner. In obtaining consent, no undue coercion or deception may be used. In South Africa some of the Reasons for the limited adherence of ethical and legal guidelines in the informed consent process were identified as language barriers, lack of administrative support, workload, and large numbers of patients (Chima, 2013).

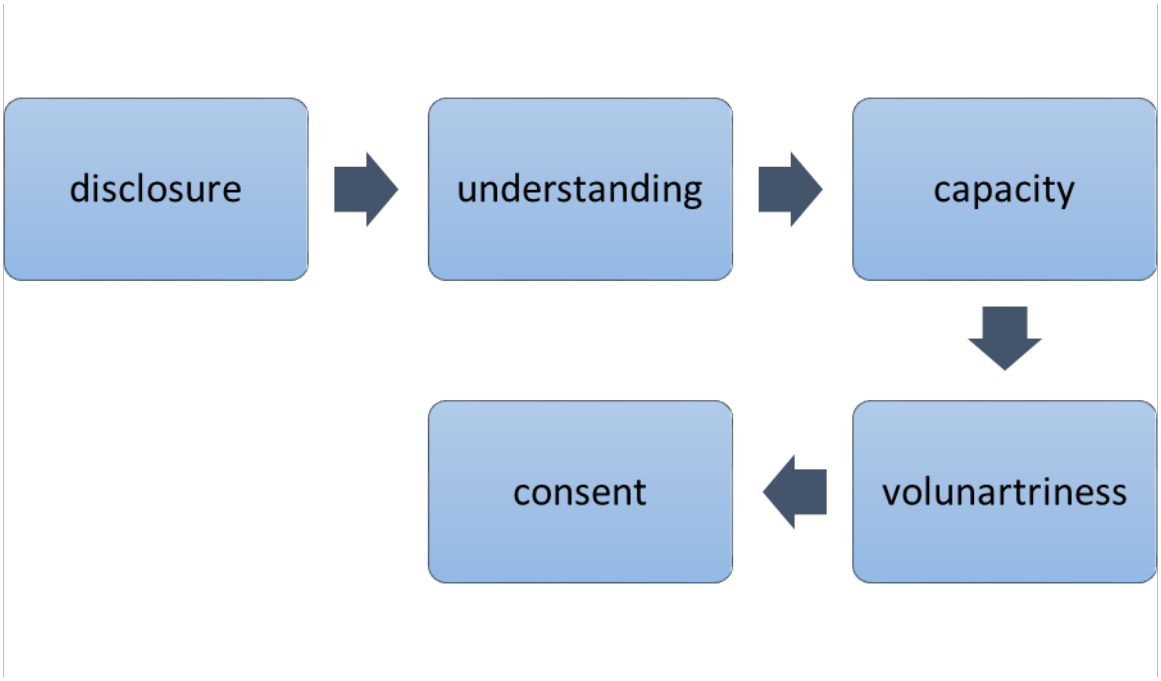

Figure 1: The principles of informed consent

The principles and process of informed consent

Exceptions to informed consent include: Presumed consent, this occurs when the patient is incapacitated and there is no power of attorney present and healthcare practioners presume that patients would want to receive care. Implied consent refers to those routine and innocuous tests or treatments that are considered to have little or obvious risk. Waived consent occurs when patients willingly hand over the decision-making power to the healthcare practitioner as they do not want to be burdened with detailed information and difficult decisions. Incompetence refers to case whereby patient lack the capacity to understand the information given and/or cannot make an informed decision and therefore, an authorized representative is necessary. Lastly therapeutic privilege occurs when the physician believes that the process of being informed and providing consent will be so detrimental to patient that standard consent cannot be obtained (Fost, 2016).

The use of technology and multimedia in the consent process would be greatly beneficial in the patient orientated process of informed consent, so popular in today's world. FDA introduced new guidelines mandating the principles of informed consent to be present in both pen and paper and electronic versions, and this information must be fully understood by the patient. These guidelines should be included in the informed consent process. This includes a description of the clinical investigation, the risks and discomforts that come with the procedure, the benefits of the procedure, any alternative treatments available, confidentiality, compensation, and medical treatment in the case of injury, contact info for queries, patient understanding and voluntariness and a total number of other patients that are in the study, how many others have received the treatment. Although there have been few studies investigating the effectiveness of technological assisted informed consent processes, results showed an improvement in patients understanding (Litwin, 2016).

Due to language barrier and a high rate of illiteracy among a wide range of population in South Africa, electronic informed consent might not be feasible for the local setting.

Challenges of Informed Consent

Informed consent has become basic requirement for research involving human participants. Before clinical or social research commence, participants need to be informed and decide to participate. Despite its importance and critical role in health research, informed consent still encounters several challenges; these include language barriers, cultural variations, religious believes, children and other vulnerable groups, research expectations by participants (Nijhawan et al., 2013).

Ethics in medical education

The knowledge of biomedical and research turned to be an essential and critical component in the recent medical practice due to the fast evolution and development of medicine, cultural diversity and increasing perception of ethics globally. The basic principles of ethics include autonomy, beneficence, non-maleficence and justice remains the major emphasis by all codes and regulations of ethics; more ethical values include integrity ,confidentiality and compassion (Nicolaides, 2016). Despite the very long history of medical ethics, it has only been formally included in educational curricula in the past 30 years (Miles, Lane, Bickel, Walker, & Cassel, 1989).

In the United States, medical ethics education became an integral part of undergraduate education in 1990, this was followed by the United Kingdom in 1993 and was strongly supported by general medical council (GMC) (Fox, Arnold, & Brody, 1995; Fulford, Yates, & Hope, 1997; Pellegrino, Siegler, & Singer, 1990). The World Medical Association has strongly recommended that ethics and human rights should be part of the curricula of medical schools around the world. Despite the general consensus regaridng medical ethics eduation , there is disagreement of the methods and approahces that meet the cultural variaitons of different communites (Goldie, 2000). In India teaching of medical ethics was nglected for a long time , currently medical council of India has recommended and introduced ethics training in different levels of medical education (Kalantri, 2003).

In their study, Mohammad, et al. (2011) administered a questionnaire regarding the knowledge, beliefs, and attitudes towards bioethics to 200 consultant physicians, senior residents, and junior residents at Jawaharlal Nehru Medical College in India. The results of the study showed that senior faculty were significantly more aware of ethical guidelines and IECs than junior residents. Furthermore, senior faculty are more likely to take informed consent. Both junior residents and senior staff encountered ethical issues in their clinical practice and research. In addition, senior faculty reported having more ethical issues than junior residents, however, this may be because junior residents refer to senior staff. This finding emphasizes the need for ethics education at all levels. Most of the residents expressed a need for a bioethics curriculum to be implemented. Furthermore, there was a significant negative correlation between ethical problems encountered and year of residency, where later year residents experience more ethical problems than newer residents, this may be due to an increase in research activities and an overemphasis on minor dilemmas (Mohammad et al., 2011).

In South Africa, the teaching of ethics in medical schools is deficient, lacking consistency and highly variable. Health professions council of South Africa (HPCSA) is attempting to develop educational modules and a curriculum of ethics that can be implemented at all institutions. Medical ethics should also be a requirement of accreditation of any medical postgraduate training programme (Nicolaides, 2016).

In a study conducted by Coetzee et al, to assess the content and pedagogy around undergraduate research ethics education in the health sciences in South Africa. The results showed that ethics education is only available in the final or final two years of undergraduate study. Furthermore, in the fourth year of study students are required to hand in a proposal, a full project including empirical report and outcomes, however only four of the eight seperate research courses require a full proposal and an informed consent document, which is said to be the cornerstone of good ethical practice. Furthermore, it was also indicated that students struggle to complete a full research project in their last year of study and therefore should be started in their third year of study. It was also noted that the research ethics lecturers and supervisors themselves had not received adequate research ethics training and are therefore ill equipped for teaching the topic. The study concluded that research ethics should be introduced into the curriculum at an earlier level of undergraduate study and there is need for educator training (Coetzee, Hoffmann, & de Roubaix, 2015).

Medical ethics is a necessary inclusion in any medical curriculum. However undergraduate and post graduate curricula do not often include or specify ethics as training requirement. Ethics has become increasingly important in the practice of modern medicine, in public policy as well as in health research.

Models of ethics education

There are several models and recommendations of why to teach medical ethics and what the learner needs to know. In 1989, Miles and colleagues identified goals of ethics in medical education “To teach doctors to recognize the humanistic and ethical aspects of medical careers; to enable doctors to examine and affirm their own personal and professional moral commitments; to equip doctors with a foundation of philosophical, social and legal knowledge; to enable doctors to employ this knowledge in clinical reasoning; to equip doctors with the interactional skills needed to apply this insight, knowledge and reasoning to human clinical care” (Miles et al., 1989, p. 705)**.**

In the UK, the GMC, in Tomorrows' Doctors, stated that students by the end of the medical curriculum should, “acquire a knowledge and understanding of ethical and legal issues relevant to the practice of medicine, and an ability to understand and analyse ethical problems so as to enable patients, their families, society and the doctor to have proper regard to such problems in reaching decisions” (Goldie, 2000, p. 109). Implementation of these goals and values should result in the practice of more ethically orientated health care professionals and medical practice.

The training of medical/research ethics should be a continuous process (Miyasaka, Akabayashi, Kai, & Ohi, 1999; Ravindran, Kalam, Lewin, & Pais, 1997; Selvakumar & Joseph, 2004). The training of research and biomedical ethics is lacking in the undergraduate and postgraduate levels of most institutions. The question of “when to introduce ethics teaching?” is a participant of many discussions. Although there is no clear answer, the common curriculum needs to be introduced in undergraduate programs and should be reinforced in postgraduate training programs. In addition, sources of knowledge of biomedical and research ethics should include a variety of approaches and methods that range from lectures, short courses, workshops, and training to diplomas and degrees. Other forms of teaching ethics also include books, journals and online certificates (Goldie et al., 2000).

In South Africa, while the need for ethics training is evident, there is no formal, well-structured ethics training and only few institutions can offer such programs. Nevertheless, ethics education is provided as short courses or workshops or as part of scientific conferences or meetings. The Health Professions Council of South Africa (HPCSA) recommends that health professionals should be aware of regulations and guidelines of biomedical ethics (Behrens & Fellingham, 2014).The formulation and design of an ethics/research ethics education program is a continuous process where goals and objectives need to be defined. Resources should be available and monitored, such as audio-visual aids and online courses and teaching ethics should include interactive sessions as the integration of knowledge into practice is essential (Ramesh, 2007).

The dissemination of information and education should be undertaken in a structured manner in order to ensure messages are not distorted and that objectives are truly attained.

Rationale of the study

One of the problems with ongoing education and training in research ethics, is that little is known about levels of knowledge of research ethics among health professionals.

This study aims to explore the familiarity and awareness of codes and regulations related to the conduct and practice of ethical research among health care professionals at Greys hospital and other health researchers affiliated with the University of KwaZulu-Natal in order to guide training in research ethics among health professionals at the University of KwaZulu-Natal.

2 METHODOLOGY

2.1. AIM OF STUDY

This is a survey based study aimed to explore familiarity and awareness of codes and regulations related to the conduct and practice of research ethics among health care professionals at Greys Hospital.

2.2. OBJECTIVES

1. To establish the reported and actual level of knowledge of ethical principles among researchers and non-researchers at Greys hospital.
2. To establish the association between the level of training and knowledge of research ethics of participants in this study.
3. To establish the relationship between the knowledge of research ethics and research experience, professional level, gender and age.
4. To establish the difference in reported and actual knowledge of research ethics among different professional groups.

2.3. STUDY DESIGN

This is a survey based study using a correlational design. Correlational designs are also known as relational designs and measure the relationship or degree of association between two or more variables.

2.4. STUDY MATERIALS AND PROCEDURE

A 20-item self-administered structured questionnaire about the actual and reported knowledge of health research ethics and the role of an ethics committee in the healthcare system was developed and validated partially from previously used surveys with permission (Hariharan et al., 2006; Mohammad et al., 2011).

These twenty items covered a variety of questions about research ethics relevant to health research. The opening part of the questionnaire consisted of demographics such as age, gender, occupation, work and research experience, and academic level. The rest of the questions explored the familiarity and awareness of research ethics; participants were requested to answer questions concerning Research Ethics Committees, sources of knowledge of research ethics, informed consent, and codes and guidelines of research ethics, etc. (appendix 3). Responses were provided in Likert scale of 1 to 4 for reported knowledge (1-very well, 2-well, 3-little, 4-not at all), whereas actual knowledge based questions were assigned score of 0 or 1 for each question (answers were Yes or No).

This questionnaire was distributed and collected via e mail and by personal correspondence to heads of departments and various categories of staff at Greys hospital in Pietermaritzburg (Tertiary care hospital). Participants included doctors of various levels (consultants, registrar, and medical officers), nurses, radiographers, dieticians, physiotherapists, occupational therapists, and pharmacists.

2.5. SAMPLING

Convenience and snowball sampling methods were used in this study in an attempt to get participants from various categories of health professionals from Grey's hospital specifically. According to Terre Blanche, Durrheim and Painter (2006) convenience sampling refers to any non-probability form of sampling whereby a population is available and convenient. Snowball sampling refers to the accumulation of respondents through contacts and networking.

2.6. ETHICAL CONSIDERATIONS

Collaborative partnership

Permission to conduct this study was obtained from Grey's Hospital and the department of Health (appendices 4 and 5). Permission was necessary to obtain as medical health professional staff were recruited from the institution of Grey's Hospital. This research may aid in the healthcare departments creation of policy regarding knowledge of research ethics for researching healthcare professionals.

Social value

Research ethics knowledge should be of great value to health care professionals, especially for those involved in clinical research or research in general. This study aimed to assess how much research ethics knowledge healthcare professionals have, which may indicate if further training in the area of research ethics is necessary particularly for those healthcare professionals who are involved in research. Dissemination of this research may aid in enhancement of knowledge regarding knowledge of healthcare professionals which subsequently could potentially inform policy.

Scientific validity

The validity and reliability of this study will be reviewed in more detail further in this chapter, however, the study design used in this research was logical and the conclusions drawn regarding knowledge of research ethics amongst healthcare professionals at Grey's hospital may be reliable.

Fair selection of study population

The study population from which the sample was drawn was all the health care professionals at Grey's hospital, in particular those that are or were involved in research. There were no vulnerable participants sampled in this study.

Favourable risk-benefit ratio

There were no known risks or benefits that might have occurred from participation.

Independent review

This protocol was submitted to the Biomedical Research Ethics Committee (BREC) at University KwaZulu-Natal (UKZN) and was conducted in accordance with the International Committee for Harmonization (ICH) Good Clinical Practice (GCP) guidelines (ICH and GCP guidelines 1996) and South African GCP (Department of Health, 2006) as well as the Declaration of Helsinki (amended in Edinburgh, 2013). Approval from the BREC was obtained in the 23 December 2015 and the approval reference code is BE473/15.

Informed consent

All participants were given an information sheet explaining the aims of the study and asked to sign a consent form after reading the information sheet. All participants were competent and understood the requirements of the study and gave their consent to participate voluntarily.

Respect for recruited participants and study communities

Participation in this study was voluntary, and participants were free to withdraw from this study at any time. There were no inducements or compensation offered to participants. No names were required, so anonymity and confidentiality was ensured.

2.7. DATA ANALYSIS

All data analysis was conducted using the Statistical Package for the Social Sciences 20 (SPSS). Once data was collected it was captured into SPSS and cleaned and some variables recoded. All questionnaires were assigned serial numbers which were captured as case numbers in SPSS. The recoding of certain variables is discussed below. The descriptives of demographics were calculated first. Descriptive statistics including means, frequencies and percentages were used to describe all variables in the study. Pearson's coefficient was used for bivariate correlation analysis. One way analysis of variance (ANOVA) was used to test differences between various categories of health professional.

Objective 1

The independent variable used in the analysis of objective one, was research experience. This variable was adopted from the question "what research experience have you had?" in the questionnaire. The question required respondents to select their highest level of research experience from the options in the table below. To create the variable of research experience, these initial items were collapsed into a three-tiered variable with the value labels as indicated below.

Table 1: Recoded variable research experience

Question options for respondents	**New variable - Research Experience – value labels**
None	No research experience
Undergraduate research assignments	Some research experience
Postgraduate research project/dissertation	
Active member of a research team	Very experienced
Lead researcher on a project	

To create the dependant variables actual and reported knowledge, selections of questions from the questionnaire were collated in SPSS i.e. the scores were tallied from each item. For dichotomous items, participants scored a zero if they answered no or failed to answer the question correctly and one if they answered yes or correctly; for questions where respondents were asked to list or select correct responses from a list, they scored one for each correct response; Likert scale items were scored with a zero for least agreement or knowledge of the particular item and a four most agreement or knowledge. For the dependant variable, actual knowledge, the following questions were used.

Table 2: Questions making up variable, actual knowledge

Question	**Response Format**
Could a non-medical person be a member of your REC?	Dichotomous
Do all studies involving human participants need to be reviewed by REC?	Dichotomous
What are the four elements of informed consent?	List
The ethical conduct of research is important because it helps to avoid legal action	Dichotomous
The ethical conduct of research is important because it helps to protect research participants	Dichotomous
How long should research be stored	Numerical
Which of the following is generally considered a vulnerable participant in need of special protection in research	Selection from a list

For the dependant variable of reported knowledge, the following questions were used

Table 3: Questions making up variable, reported knowledge

Question	**Response Format**
I have taken the Hippocratic oath	Alternate choice
I know the contents of the oath	Alternate choice
How well do you know the following ethical guidelines	Likert scale
Are you aware of IEC in your institution	Alternate choice
Are you aware of the composition of your IEC	Alternate choice
How aware are you of the ethical concepts of coercion and inducement	Likert scale
Are you familiar with the concept of research misconduct collectively known as FFP	Alternate choice

In the analysis of objective one a bivariate correlation using Pearson's coefficient was used to test the association between actual and reported knowledge. A one-way analysis of variance (ANOVA) was conducted, with research experience as the independent variable and actual and reported knowledge as the dependant variables.

Objective 2

The variables used in the analysis of objective two consisted of actual and reported knowledge and level of training. The variable, level of training, was calculated from the question, “What has been the source of your knowledge of biomedical and research ethics?” In this question participants were asked to indicate their level of training or source of knowledge from the options indicated in the table below. These items were initially coded as separate variables, due to a lack of mutual exclusivity, where a negative response was coded as ‘0’ and a positive response as ‘1’. However, for this analysis the items needed to be collated into one ordinal variable containing all of these items as value labels. In order to calculate this variable, the items first had to be ordered in terms of level of training. Subsequently, if respondents said yes to having completed a degree or diploma regardless of having any other level of training, they were coded with a six. If respondents had not received a degree or diploma but had attended a conference or symposium regardless of any other training experience they were coded with a five. This continued down the order of training level where respondent who indicated no training level received a score of zero. Below is a table indicating the method used for coding this variable.

Table 4: Coding scheme for variable, level of training

Option chosen	**Value given**	**6**	**5**	**4**	**3**	**2**	**1**	**0**
Degree/Diploma/Certificate		1	0	0	0	0	0	0
Conferences and symposiums			1	0	0	0	0	0
Short course/ workshops				1	0	0	0	0
In-service training					1	0	0	0
Online certificates						1	0	0
Books/Journals							1	0
No knowledge		0	0	0	0	0	0	1

To analyse objective two, two bivariate correlations using Pearson's coefficient were run. The first compared actual knowledge with level of training, and the second compared reported knowledge with level of training.

Objective 3

In the analysis of objective three a bivariate correlation using Pearson's coefficient was conducted exploring demographic variables of age, gender, academic level, and research experience with reported and actual knowledge.

Objective 4

In the analysis of objective four the variable of occupation was recoded. Doctors made up the largest occupation subgroup, with 55.35% of the sample, nurses then made up the second largest occupation subgroup, no other occupation subgroup exceeded 8% of the sample and so all other occupations were collapsed into one subgroup known as "other staff".

A one-way ANOVA was conducted with occupation as the independent variable and reported and actual knowledge as the dependant variables. Post hoc pairwise comparisons were also made using both Tukey's HSD and Fisher's LSD, in order to test the specific differences identified.

2.8. VALIDITY, RELIABILITY AND GENERALISABILITY

Reliability of the instrument

When assessing the validity of a scale or instrument of measurement, it is important to determine whether the instrument measures what it claims to. For this study, as the instrument of measurement is based on previous measures used in a similar area of study, it can be said that the questionnaire has criterion validity. Criterion validity is established by comparing the measure used with other measures known to assess the same criterion. Furthermore, the instrument of measurement also has content validity as it tests a very specific domain that is knowledge (reported and actual) of research ethics.

Internal and external validity of study

According to Terre Blanche et al. (2006) relational studies indicate how one variable is associated with another and does not necessarily indicate cause and effect, thus making this type of study vulnerable to the threat of extraneous or confounding variables. Extraneous or confounding variables are any variables not manipulated by the researcher that may influence changes in the dependant variable (Terre Blanche, Durrheim, & Painter, 2006). It was expected that variables such as involvement in research, age and level of study would be confounding variables in the relationship between occupation and level of knowledge of research ethics, and therefore seperate correlations were conducted to assess this.

External validity

According to Terre Blanche et al. (2006) the external validity of a study refers to how it can be generalised to the greater population. According to the information obtained from the department of human resources at Greys Hospital, the division of the population by healthcare profession occupation is as follows: doctors - 19.15%, nurses – 70.71%, and other staff – 10.13%. The sample obtained from the population of staff at Greys Hospital does not represent the population divided by occupation as the proportion of doctors in the sample over-represented doctors in the population, and sampled nurses under-represented the population. Other staff were also over-represented in the sample as they contributed to a greater proportion in the sample. This misrepresentation can be seen in table 6.

Table 5: Proportions of staff population and sample

	Population proportion of healthcare professionals	Sample proportion of healthcare professionals
Doctors	19.15%	55.34%
Nurses	70.71%	12.62%
Other staff	10.14%	32.04%

The misrepresentation of occupation proportions may be due to sample bias, where only particular staff were able to complete and return the questionnaire. Furthermore, doctors may be over-represented as they were specifically targeted as generally having more research experience through clinical trials than other occupations. Therefore, doctors would have provided greater insight regarding research ethics knowledge than generally non-researching occupations. It was shown that doctors tended to have greater research experience in the results produced in this study, this may be seen in the results chapter of this paper (see Chapter 3).

According to Terre Blanche, Durrheim and Painter (2006), the reliability of a measure is determined by how consistently it measures a particular construct. The questionnaire used in this study was adapted from the questionnaire created by Hariharan et al. (2006) and Mohammad et al. (2011). No reliability statistics were available in these papers or from direct contact with the authors. Therefore, in order to test the reliability of the instrument it is suggested that a future meta-analysis investigating the reliability of other measures as well as this one, be conducted.

As this was a convenience sample, rather than a random sample, there are limitations on the generalization of findings.

3 RESULTS

3.1. RESPONSE RATES

Of the 152 questionnaires distributed via email and personal contact, 103 were returned with a total response rate of 67.7%. Of the 16 heads of departments or clinical units, five responses were collected (31.25%). Doctors contributed 55% of all responses, this included consultants, registrars, and medical officers. The next biggest contributors to the study were nurses with 12.6%. The rest of response rate per occupation are reported in table 7.

Table 6: Response Rates per occupation

	Responses	Total distributed	Response rate (%)
Medical consultant	29	41	70.73170732
Medical registrar	6	9	66.66666667
Medical officer	22	22	100
Nurse	13	21	61.9047619
Radiographer	7	9	77.77777778
Dietician	4	10	40
Pharmacist	8	20	40
OT	5	9	55.55555556
Other	9	11	81.81818182
	103	152	67.76315789
Total			67.76315789

3.2. DEMOGRAPHICS

In total 103 responses were collected, from various healthcare professionals working at Greys hospital in Pietermaritzburg, between January and February 2016. The most common occupation amongst respondents was that of doctors in general contributing to 55.35% of the entire sample, whilst consultants specifically contributed to 28.16% of the sample, medical officer doctors 21.36%, and registrar doctors 5.83%. Both physiotherapy and medical technologist were the least frequently held positions at 1.94%. No social workers, psychologists or lab technicians completed the questionnaire and therefore were left out in the main analysis. The most frequently indicated academic level was 'none' (68.93%), the most frequently reported age was 31-40 (47.57%), 65.05% of the respondents were female, 32.04% were male (see Table 8).

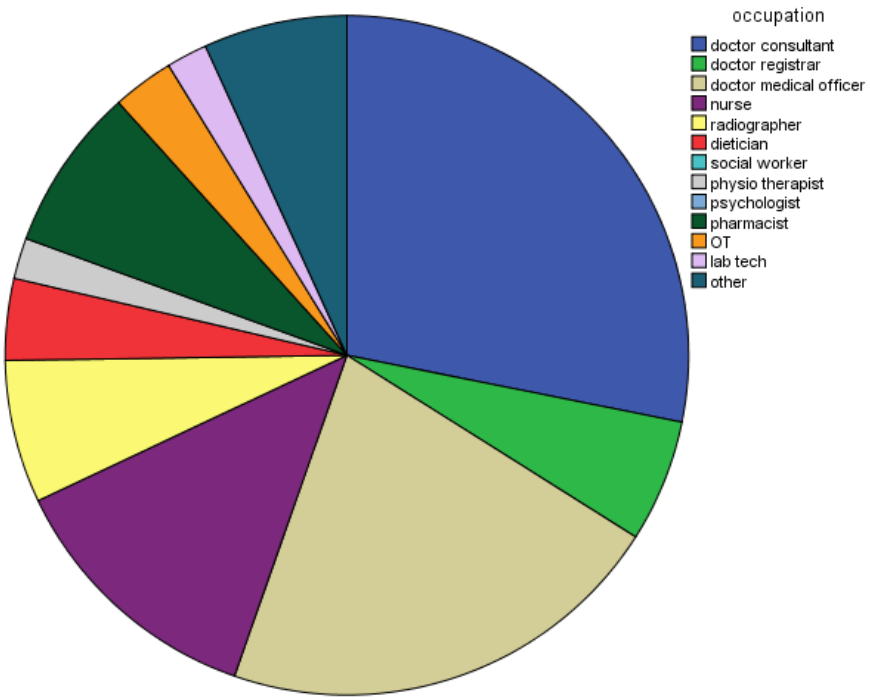

Figure 2: Demographics of respondents by occupation

Table 7: Demographic frequencies and proportions of respondents

Variable		Frequency	Percentage
Occupation		103	
	Doctor consultant	29	28.16
	Doctor registrar	6	5.83
	Doctor medical officer	22	21.36
	Nurse	13	12.62
	Radiographer	7	6.80
	Dietician	4	3.88
	Physical therapist	2	1.94
	Pharmacist	8	7.77
	Occupational therapist	3	2.91
	Other	7	6.80
	Medical technologist	2	1.94
Academic level		103	
	Missing	7	6.80
	Lecturer	17	16.50
	Researcher	8	7.77
	None	71	68.93
Age		103	
	18-25	10	9.71
	26-30	20	19.42
	31-40	49	47.57
	41-50	18	17.48
	51-60	3	2.91

	>60	3	2.91
Gender		103	
	Missing	3	2.91
	Male	33	32.04
	Female	67	65.05
Research Experience		103	
	Missing	1	0.97
	None	20	19.42
	Undergrad research	51	49.51
	Postgrad dissertation	21	20.39
	Active research team member	5	4.85
	Lead researcher	5	4.85

3.3. FREQUENCIES

Table 8: Knowledge of ethical codes and guidelines

		Not at all	Little	Well	Very well	Missing	Total
Valid	Nuremburg code	55 (53.4%)	30 (29.1%)	16 (15.5%)	1 (1%)	1 (1%)	103 (100%)
	Belmont report	75 (72%)	21 (20.4%)	6 (5.8%)	1 (1%)	0 (0%)	103 (100%)
	Helsinki declaration	53 (51%)	28 (27.2 %)	18 (17.5%)	4 (3.9 %)	0 (0%)	103 (100%)
	Institutional review boards	59 (57.3%)	33 (32%)	11 (10.7%)	0 (0%)	0 (0%)	103 (100%)
	CIOMs guidelines	79 (76.7%)	19 (18.4%)	5 (4.9%)	0 (0%)	0 (0%)	103 (100%)
	WHO guidelines	22 (21.4%)	44 (42.7%)	29 (28.2%)	8 (7.8%)	0 (0%)	103 (100%)
	South Afric department health guidelin	26 (25.2%)	46 (44.7%)	24 (23.3%)	7 (6.8%)	0 (0%)	103 (100%)
Total		52.7 (51.18%)	31.6 (30.7%)	15.6 (15.1%)	3 (2.9%)	0.14 (0.1%)	103 (100%)

The table above indicates respondents reported knowledge on each of the bioethical guidelines or reports stated in the table. Most of the respondents, who were made up of healthcare professionals from Greys hospital, had either little or very little knowledge on all the ethical codes and guidelines. The CIOMs guidelines appeared to be the least known about guidelines and the WHO ethical guidelines the most known about. A cumulative percentage of 18.6% indicates the number of respondents who know all of the guidelines well or very well, whereas 84.3% of respondents know little or very little of the guidelines.

Table 9: Are you aware of REC in your institution?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	32	31.1	32.0	32.0
	Yes	68	66.0	68.0	100.0
	Total	100	97.1	100.0	
Missing	System	3	2.9		
Total		103	100.0		

The table above illustrates the frequency of participants' responses to a dichotomous question regarding their awareness of the IEC in their institution. Of the 103 participants 32 (31%) were not aware of their IEC and 68 (66%) were aware of its existence, three (3%) respondents however failed to provide a response.

Table 10: What are the four elements of informed consent?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no knowledge	25	24.3	24.3	24.3
	knowledge of one element	21	20.4	20.4	44.7
	knowledge of two elements	23	22.3	22.3	67.0
	knowledge of three elements	15	14.6	14.6	81.6
	knowledge of all the elements	19	18.4	18.4	100.0
	Total	103	100.0	100.0	

Participants were asked to name the four vital elements of informed consent. Of the 103 participants, the majority could not name a single element, 20.4% of respondents could name at least one of the four elements and only 18.4% could name all four of the elements. The cumulative percentage of respondents who could name a maximum of three elements was 81.6%, which means that the vast majority of participants are not aware of all the elements of informed consent.

Table 11: Knowledge of how long data should be stored

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Incorrect	44	42.7	42.7	42.7
	Correct	59	57.3	57.3	100.0
	Total	103	100.0	100.0	

Participants were asked to indicate how long data should be stored after collection, and although the majority were correct in their answer a very large proportion (42.7%) of the participants could not correctly state how long data should legally be stored. This information is tabled above.

Table 12: Do you feel there is sufficient knowledge of ethics among co workers?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	94	91.3	91.3	91.3
	Yes	9	8.7	8.7	100.0
	Total	103	100.0	100.0	

Many of the participants sampled acknowledged that there is not sufficient knowledge about medical ethics amongst co-workers. This is shown by the 91.3% of respondents who answered no when asked the question of whether they feel there is sufficient knowledge of ethics among co-workers. Only 8.7% of the sample felt satisfied with their co-workers' level of knowledge regarding ethics.

Table 13: Do you feel the need for lectures, workshops, conferences to improve knowledge of ethics?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no	3	2.9	2.9	2.9
	yes	100	97.1	97.1	100.0
	Total	103	100.0	100.0	

Almost the entire sample of participants (97.1%) agreed that there was a definite need to include lectures, conferences, and workshops in the curriculum to improve ethics knowledge. Only 3% of the sample deemed it unnecessary.

3.4. RESEARCH EXPERIENCE

The frequency of the respondents' research experience was calculated and represented in figure 3. The bar chart in figure 3 indicates a slight positive skew (.905). The percentage of participants who did not respond to this particular question (indicated as 'missing' in the bar chart) was 0.971%. Participants who indicated that they had no previous research experience comprised 19.42% of the sample; respondents with undergraduate research experience made up the largest proportion at 49.51%, and respondents with postgraduate research experience comprised 20.39% of the sample. Both "being an active member of a research team" and "being a lead researcher" research experience categories held a percentage proportion of 4.854%.

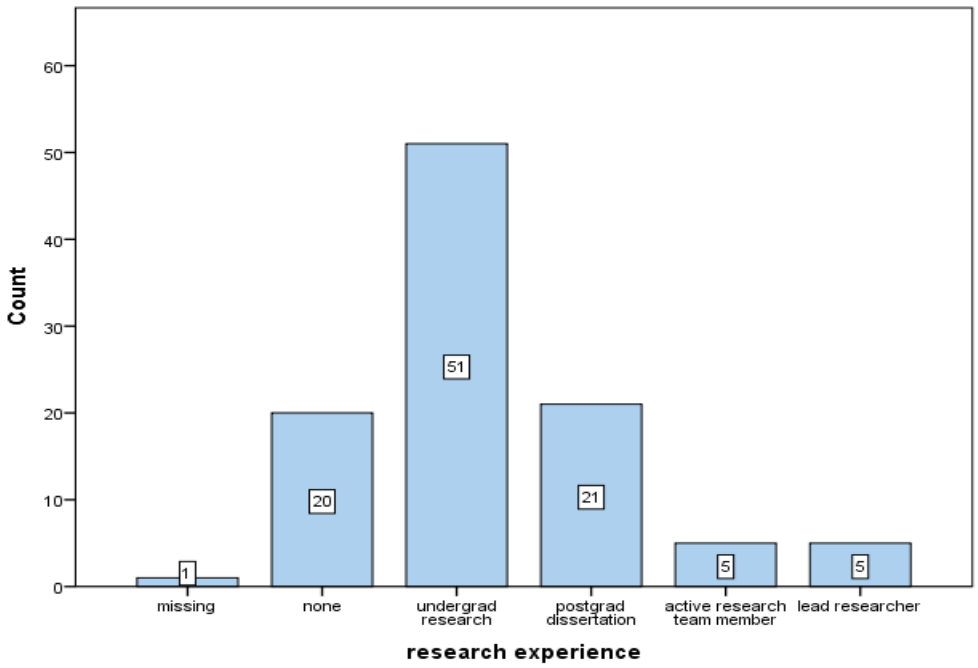

Figure 3: Bar graph indicating frequency of research experience

3.5. CONSULTATION REGARDING ETHICAL ISSUES

The cross-tabulation below indicates the proportion of respondents, differing by occupation, who consult with varying persons, institutions or sources of information when faced with ethical issues. The sources of consultation are not mutually exclusive and therefore each occupation may consult with multiple sources on ethical issues.

Table 14: Cross-tabulation of occupation and to whom they consult with ethical issues

		Occupation			Total Count
		Doctors	Nurses	All other hospital staff	
Whom to consult with ethical issue	colleague	61.4%	38.5%	30.3%	50
	supervisor	66.7%	76.9%	69.7%	71
	HOD	63.2%	7.7%	54.5%	55
	Hospital administrator	8.8%	0.0%	3.0%	6
	REC	35.1%	23.1%	27.3%	32
	Professional association	14.0%	7.7%	9.1%	12
	Internet, books	22.8%	0.0%	21.2%	20
	Medical Protection Society	33.3%	0.0%	6.1%	21
Total Count		57	13	33	103

According to the results reported in the cross-tabulation, the source of consultation with the highest proportion of consultations for ethical issues from all occupational groups was supervisor. The majority of respondents regardless of occupation reported that they would consult their supervisor regarding any ethical issues. Other popular sources of consultation regarding ethical issues were colleagues and HODs.

Only a significant proportion of doctors (33.3%) consulted with the medical protection society, whereas no nurses and only 6.1% of all other staff consulted with the medical protection society. The table below shows other sources for consultation such as REC, internet, and books; these are apparently less utilized.

3.1. REPORTED KNOWLEDGE OF RESEARCH ETHICS BY OCCUPATION

Table 17 below indicates the association of hospital occupation with knowledge of research ethics guidelines. According to the output represented in table three, doctors in general reported to be the most knowledgeable in all of the ethical guidelines. Regardless of occupation most staff members reported to be aware of the World Health Organisation ethics guidelines as well as the South African, Department of Health ethical guidelines. The guidelines which are least known by all occupations are those set out by CIOMS.

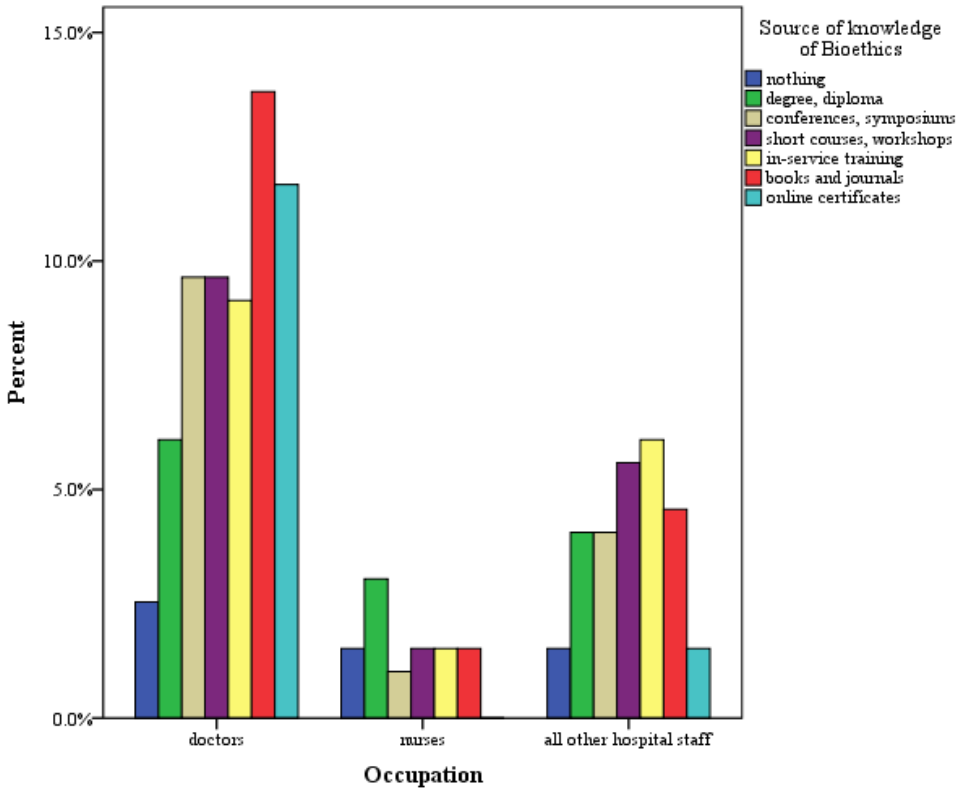

Figure 4: Source of ethics knowledge

Table 15: Cross-tabulation of occupation with knowledge of research ethical guidelines

			Occupation			Total
			Doctors	Nurses	All other hospital staff	
Knowledge of Research ethics guidelines	Nuremberg code	Count	32	4	11	47
		% within column	66.7%	30.8%	35.5%	
	Belmont Report	Count	20	2	6	28
		% within column	41.7%	15.4%	19.4%	
	Helsinki	Count	32	4	14	50
		% within column	66.7%	30.8%	45.2%	
	Institute	Count	32	4	8	44
		% within column	66.7%	30.8%	25.8%	
	CIOMS	Count	18	2	4	24
		% within column	37.5%	15.4%	12.9%	
	WHO	Count	44	11	26	81
		% within column	91.7%	84.6%	83.9%	
	Department of Health	Count	39	11	26	76
		% within column	81.3%	84.6%	83.9%	
Total		Count	48	13	31	92

3.2. REPORTED KNOWLEDGE OF RESEARCH ETHICS BY RESEARCH EXPERIENCE

The bar graph below indicates the relationship of research experience by reported knowledge of ethical guidelines. A Pearson's correlation was conducted to evaluate whether there was a significant correlation between knowledge of research ethics guidelines and research experience and the results were significant at a significance level of α= 0.01 (r=.320, p=.001). Although correlation does not indicate cause and effect relationships; this correlation does indicate that increased research experience is associated with an increase in reported knowledge about ethical guidelines.

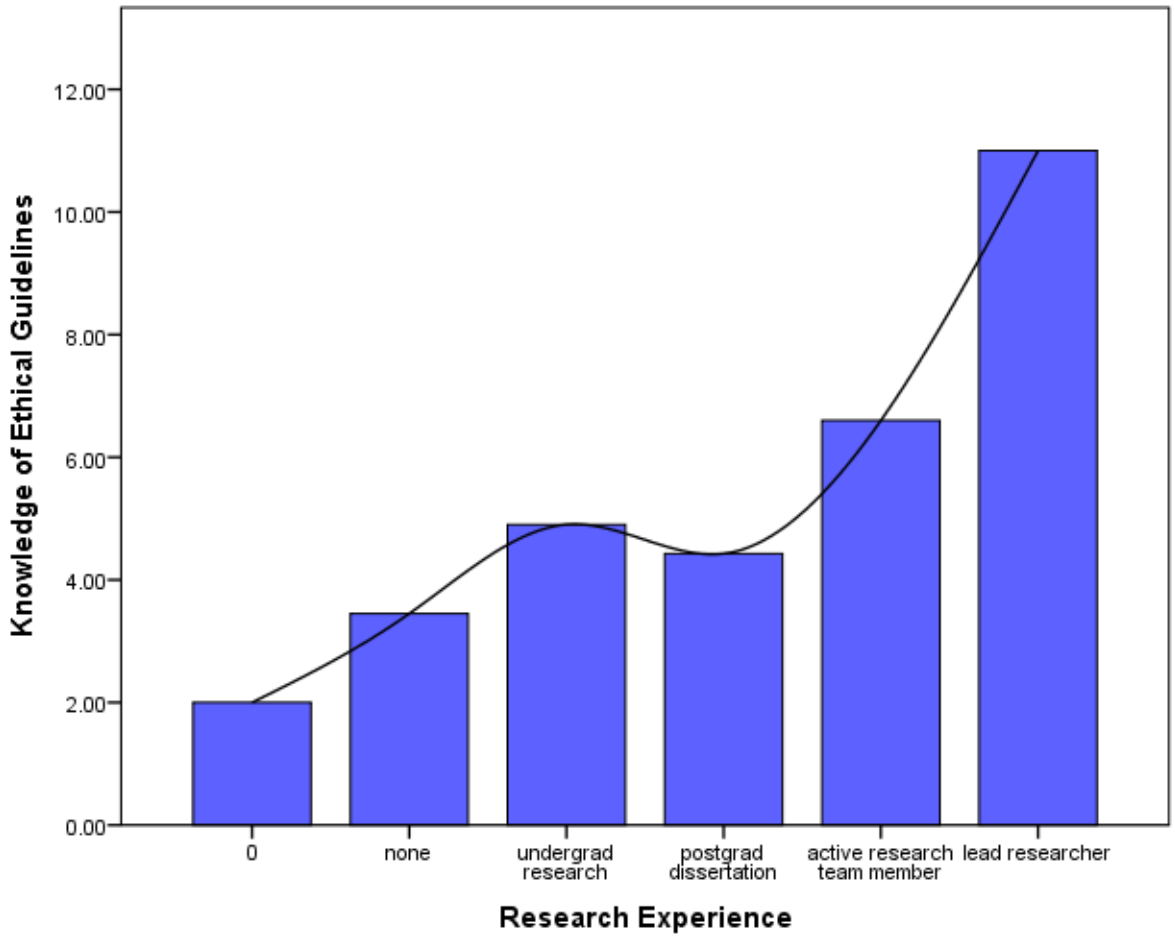

Figure 5: Reported ethics knowledge by research experience

3.3. SOURCE OF ETHICS KNOWLEDGE

The following bar chart indicates that for doctors, the greatest source of their bioethical knowledge came from books and journals, whereas for nurses, it was completing a degree or diploma. Furthermore, the most common source of bioethical knowledge for all other hospital staff was in service training. Online courses in bioethics was the second most popular source for gaining bioethics knowledge for doctors, however, this was the least used source for gaining bioethics knowledge for all other hospital staff including nurses.

3.4. FINDINGS IN RELATION TO STUDY OBJECTIVES.

Objective 1:

To establish the reported and actual level of knowledge of ethical principles among those reported researchers and non-researchers at Grey's hospital. Firstly, correlations between the two dependant variables, actual and reported knowledge were explored. According to the correlation outputs below, there is a significant correlation between the two variables (F=15.287, df=101, r= 0.363, p=.001). Furthermore, the correlation yielded a positive and significant result of 0.363, indicating that an increase in reported knowledge is associated with an increase in actual knowledge, this is an expected result. Although, reported and actual knowledge do correlate significantly, the scatterplot shown in the figure below indicates a somewhat spread-out dispersion of scores around the trend line. The $R^{2=}$ 0.131 statistic, although positive does indicate a weak to average regression to the mean.

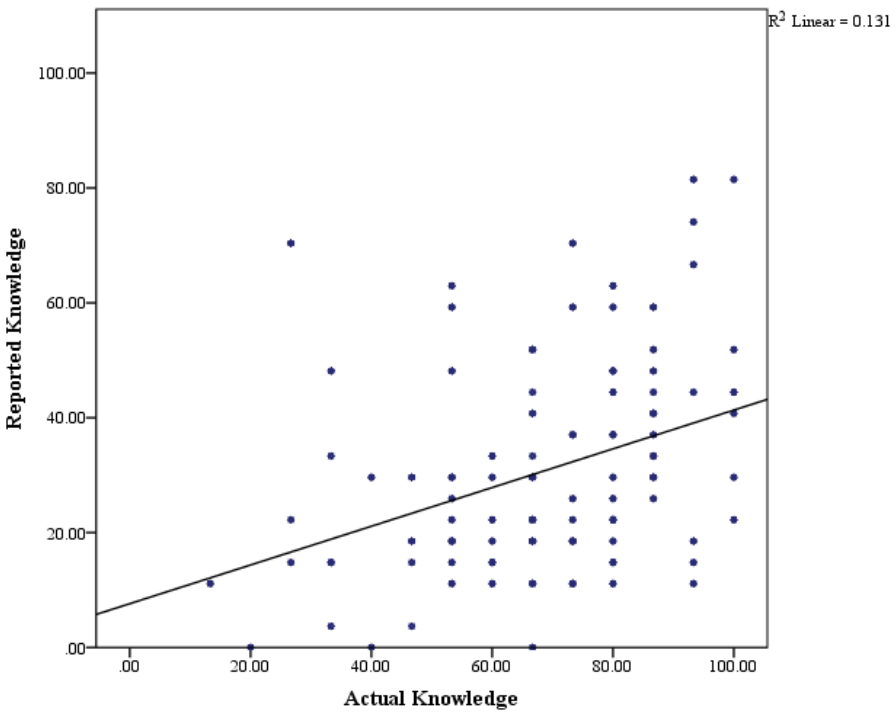

Figure 6: Correlation between actual and reported knowledge

The report below displays the mean, sample size, standard deviation, and maximum and minimum statistics for each level of research experience for both actual and reported knowledge. For the dependant variable of actual knowledge the means are relatively similar across all three levels of research experience with only slight increases. However, for reported knowledge there is a steady increase in mean size through the levels of research experience. An ANOVA analysis confirms this trend, see table 18 and 19.

Table 16: Descriptive statistics for research experience with actual and reported knowledge

		Mean	N	Std. Deviation	Minimum	Maximum
Actual Knowledge	No Experience	62.8571	21	20.60975	33.33	100
	Some Experience	69.7222	72	19.11787	13.33	100
	Very experienced	71.3333	10	23.52829	20	93.33
	Total	68.479	103	19.87311	13.33	100
Reported Knowledge	No Experience	22.3986	21	15.64683	0	59.26
	Some Experience	30.144	72	15.9127	0	81.48
	Very experienced	52.2222	10	25.44827	0	81.48
	Total	30.7084	103	18.47221	0	81.48

According to the results of the ANOVA, research experience does not significantly predict actual knowledge, however, it does significantly predict reported knowledge ($F=10.629$, $<p=.001$, $df=2$). The effect size $\eta^2 =0.175$, indicates that 17.5% of the variance between the means of the reported knowledge is attributable to the respondents' research experience.

Table 17: ANOVA, reported knowledge and research experience

			Sum of Squares	df	Mean Square	F	P	η²
Actual Knowledge * Research Experience	Between Groups	(Combined)	856.466	2	428.233	1.086	0.341	0.021
	Within Groups		39427.46	100	394.275			
	Total		40283.927	102				
Reported Knowledge * Research Experience	Between Groups	(Combined)	6101.49	2	3050.745	10.629	.000	0.175
	Within Groups		28703.203	100	287.032			
	Total		34804.693	102				

Objective 2:

To establish the level of association between training in research ethics and knowledge of research ethics of participants in this study. For the analysis of objective two a Pearson correlation was conducted between the three variables: actual and reported knowledge and level of training. Both actual knowledge ($\bar{x}$=68.48, s=19.87) and reported knowledge ($\bar{x}$=30.71, s=18.47) are significantly associated with the level of training in research ethics respondents had. The level of bioethics training was significantly associated with both actual (r=0.34, p= 0.001) and reported (r=0.342, p=<0.000) knowledge.

The association between level of training and research ethics knowledge is shown graphically in the figures below. As is visible from the first graph, reading books and journals is associated with lower levels of actual knowledge. Having no training at all indicates moderate actual knowledge, but all the other training categories indicate a similarly high level of actual research ethics knowledge. In the graph representing the correlation between reported knowledge and level of training, it is visible that there is a steady and positive trend, however with a spike in online certificates showing an association with higher levels of reported knowledge.

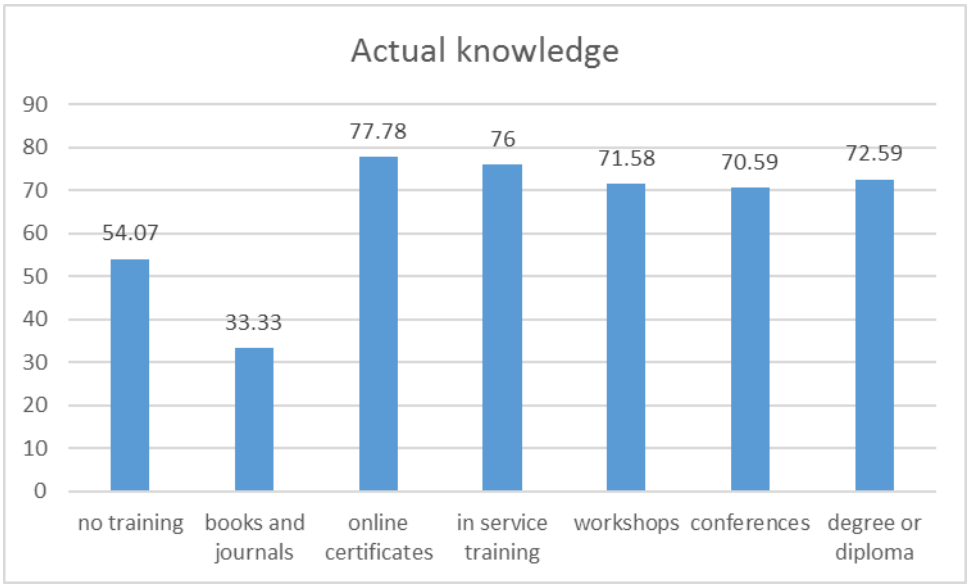

Figure 7: Actual knowledge by level of training

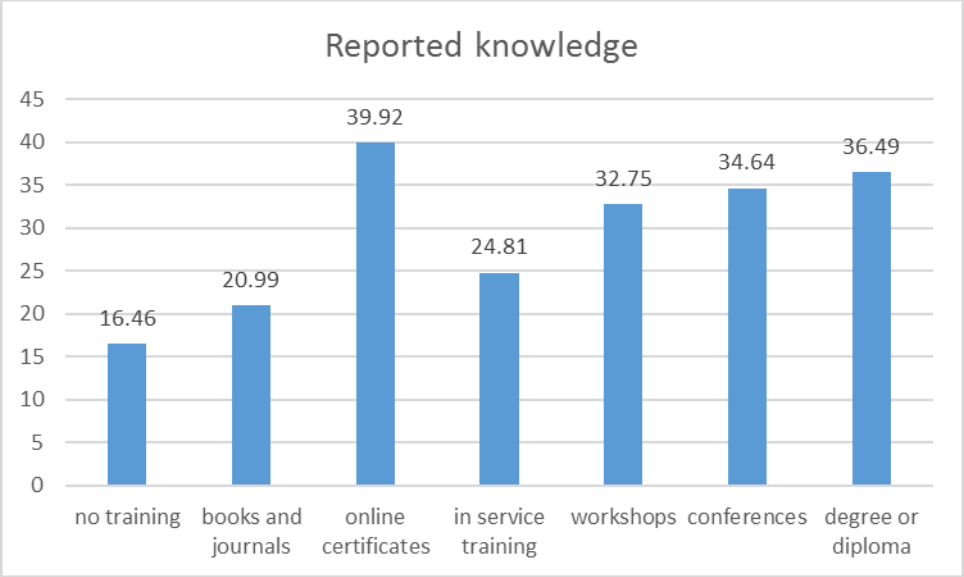

Figure 8: Reported knowledge by level of training

Objective 3

To establish the relationship between the knowledge of research ethics, and research experience and professional level. A Pearson's correlation was used to analyse objective three. According to the table below actual knowledge only correlated significantly with the academic level of the respondent. However, academic level and research experience both correlate significantly with reported knowledge. These results all indicate that those who reportedly have higher academic qualifications, and more research experience also report greater knowledge of research ethics.

Table 18: Correlation coefficients between knowledge and other demographic factors

		Age	Academic Level	Research Experience
Actual Knowledge	Pearson Correlation	0.07	-.233*	0.134
	Sig. (2-tailed)	0.479	0.02	0.178
	N	103	100	103
Reported Knowledge	Pearson Correlation	0.026	-.356**	.382**
	Sig. (2-tailed)	0.796	0.00	0.00
	N	103	100	103

Objective 4:

To establish the difference in reported and actual knowledge of research ethics amongst different professional groups.

Table 19: Descriptive statistics for Reported and actual knowledge

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Reported knowledge	Doctor	57	35.48	20.33	2.69	30.08	40.87	0	81.48
	Nurse	13	25.07	15.21	4.22	15.88	34.26	11.11	62.96
	other staff	33	24.69	13.66	2.38	19.85	29.54	0	51.85
	Total	103	30.71	18.47	1.82	27.10	34.32	0	81.48
Actual knowledge	doctor	57	72.75	18.87	2.50	67.74	77.75	26.67	100
	Nurse	13	59.49	16.88	4.68	49.29	69.69	33.33	80
	other staff	33	64.65	21.18	3.69	57.14	72.16	13.33	100
	Total	103	68.48	19.87	1.96	64.60	72.36	13.33	100

Table 20: One-way ANOVA for Reported and Actual knowledge

		Sum of Squares	df	Mean Square	F	Sig.
Reported knowledge	Between Groups	2904.340	2	1452.170	4.552	.013
	Within Groups	31900.353	100	319.004		
	Total	34804.693	102			
Actual knowledge	Between Groups	2574.852	2	1287.426	3.414	.037
	Within Groups	37709.075	100	377.091		
	Total	40283.927	102			

According to the One-way ANOVA output above, there is at least one significant difference between the three occupations (doctors, nurses and other staff) regarding reported knowledge at the significance level of α=0.05 (F=4.552, df=2, p=.013). Furthermore, the outputs also indicate at least one significant difference in actual knowledge between the three occupations (F=3.414, df=2, p=.037). Owing to the significance of the F value in both comparisons, post hoc multiple comparisons using Tukey's HSD and Fisher's LSD were conducted. According to the multiple comparisons reported for both Tukey's HSD and Fisher's LSD, there is a significant difference in the reported knowledge between doctors and other staff members with doctors reportedly knowing more regarding bioethics (Tukey's HSD: p=.019; Fisher's LSD: .007). Tukey's HSD did not reveal any pairwise differences between the occupations for actual knowledge, however due to the significant F value in the one-way ANOVA Fisher's LSD was also run and A significant difference between doctors and nurses was found (p=.029) at a level of α= 0.05 with doctors having significantly more actual knowledge of bioethics.

Table 21: Post hoc comparisons for reported and actual knowledge

Dependent Variable		(I) Occupation	(J) Occupation	Mean Difference (Lin et al.)	Std. Error	Sig.	95% Confidence Interval	
							Lower Bound	Upper Bound
Reported knowledge	Tukey HSD	Doctor	nurse	10.40636	5.48956	.145	-2.6539	23.4666
			other staff	10.78622*	3.90683	.019	1.4914	20.0810
		Nurse	doctor	-10.40636	5.48956	.145	-23.4666	2.6539
			other staff	.37987	5.84855	.998	-13.5345	14.2942
		other staff	doctor	-10.78622*	3.90683	.019	-20.0810	-1.4914
			nurse	-.37987	5.84855	.998	-14.2942	13.5345
	LSD	Doctor	nurse	10.40636	5.48956	.061	-.4848	21.2975
			other staff	10.78622*	3.90683	.007	3.0352	18.5373
		Nurse	doctor	-10.40636	5.48956	.061	-21.2975	.4848
			other staff	.37987	5.84855	.948	-11.2235	11.9832
		other staff	doctor	-10.78622*	3.90683	.007	-18.5373	-3.0352
			Nurse	-.37987	5.84855	.948	-11.9832	11.2235
Actual knowledge	Tukey HSD	Doctor	Nurse	13.26136	5.96847	.072	-.9383	27.4610
			other staff	8.10207	4.24766	.142	-2.0036	18.2077
		Nurse	doctor	-13.26136	5.96847	.072	-27.4610	.9383
			other staff	-5.15929	6.35877	.697	-20.2875	9.9689
		other staff	doctor	-8.10207	4.24766	.142	-18.2077	2.0036
			Nurse	5.15929	6.35877	.697	-9.9689	20.2875
	LSD	Doctor	Nurse	13.26136*	5.96847	.029	1.4201	25.1026
			other staff	8.10207	4.24766	.059	-.3252	16.5293
		Nurse	doctor	-13.26136*	5.96847	.029	-25.1026	-1.4201

			other staff	-5.15929	6.35877	.419	-17.7749	7.4563
		other staff	doctor	-8.10207	4.24766	.059	-16.5293	.3252
			nurse	5.15929	6.35877	.419	-7.4563	17.7749
*. The mean difference is significant at the 0.05 level.								

4 DISCUSSION

The knowledge of research ethics is of great importance in biomedical research and medical practice. Codes and guidelines have been developed partially as a result of unethical research and exploitation of human participants that dates back to ancient times, however unethical research is still of concern today. Despite the very long history of medical ethics, it has only been formally included in educational programs in the past 30 years (Miles et al., 1989). Several ethical issues are involved in research with human participants, some of which include informed consent, REC, and storage of tissue material.

There is no consensus regarding what constitutes appropriate ethics knowledge that should be taught in undergraduate and postgraduate training programs (Goldie, 2000).

Some studies have addressed the importance of knowledge and awareness of research ethics among health care professionals, however the literature is scarce with respect to this. The purpose of this study is therefore to assess the knowledge and familiarity of health research ethics in a group of health care professionals at Greys hospital.

In this study, we directed our research towards the assessment of knowledge of the basic principles of research ethics. The results of our data analysis clearly showed a wide variation in knowledge and perception between different categories of participants. The respondents in the sample were representative of various categories of health care professionals including doctors of different levels, nurses, physiotherapists, dieticians, and pharmacists. Doctors were the predominant group in the sample whilst female participants outnumbered males.

4.1. ACTUAL KNOWLEDGE:

The question of informed consent focused on whether participants are aware of its principles and components. Participants were asked to name the four vital elements of informed consent. Results showed that the majority of participants were not aware of the elements of informed consent. Most participants could acknowledge the components of informed consent regarding information disclosure and voluntariness, but many did not identify competence and understanding. This is in contrast to a study conducted in Malaysia which showed high level of awareness of informed consent amongst health care professionals (Rathor et al., 2007). This suggests that perhaps healthcare professionals in Malaysia have a better research ethics training programme that may aid in developing local policies and research ethic curricula.

4.2. REPORTED KNOWLEDGE

Participants were asked to indicate whether they had taken the Hippocratic Oath (or nurse's oath). Results showed that one third of respondents had not taken the oath. Although the Hippocratic Oath was introduced more than 2500 years ago, as the pledge of ethical conduct, many health care professionals are still not aware of the oath or its contents. In a study by M Mohammad et al, approximately 70% did not take the Hippocratic Oath, in comparison to results from our study (Mohammad et al., 2011).

The findings of this study clearly indicated an inadequate reported knowledge of research ethics guidelines. Most of the respondents reported either little or very little knowledge of all the ethical codes and guidelines. The CIOMs guidelines appeared to be least known, whereas WHO ethical guidelines the most known. Doctors appeared to be the most knowledgeable participants, however, their knowledge is still deficient. These results were expected and shows that ethics training is either ineffective or possibly non - existent. These results were expected as other studies have shown similar results (Mohammad, et al., 2011; Hariharan, et al., 2006).

The source of knowledge is widely variable between participants, most respondents obtained their knowledge of ethics from multiple sources. Books, online courses, seminars, and short workshops formed the most commonly used sources. Less than 5% of participants had formal ethics training in the form of degrees or diplomas. Most of the respondents reported that their research experience was received as part of their undergraduate studies.

These results raise important concerns, such as participants are mostly self-taught and that the teaching of ethics is lacking and inconsistent. Other studies have also found that health care professionals have limited exposure to research ethics education (Hariharan et al., 2006; Mohammad et al., 2011). Health research and medical ethics needs to be introduced to the curriculum of undergraduate and postgraduate programs as a matter of urgency.

One third of participants are not aware of the research ethics committee and its existence at Greys hospital. The majority are not aware of the REC's role, function, and composition. This could be attributed to the limited function of the committee in the institution and a lack of basic knowledge about research ethics committees by participants. These findings confirm results of other studies from India, West Indies, and the United States of America (Brogen, Rajkumari, Laishram, & Joy, 2009; Hariharan et al., 2006; Hern Jr, 1989).

Health care professionals encounter a wide spectrum of issues pertaining to research and medical practice, therefore dilemmas in ethics is a common challenge. Our results, similar to other studies, have shown that the majority of respondents prefer to consult their supervisors first followed by their Heads of departments and colleagues, whilst one third preferred to consult with the medical protection society (Hariharan et al., 2006; Mohammad et al., 2011).

4.3. ASSOCIATION BETWEEN KNOWLEDGE, TRAINING AND RESEARCH EXPERIENCE

The knowledge of research ethics was correlated to the level of training in research ethics. Results showed that both reported and actual knowledge have a significant positive relationship with the level of training in research ethics. Participants who claimed to have some training in research ethics either tertiary or in the form of workshops or conferences showed an increase in reported and actual knowledge. For those however, who claimed they obtained their knowledge from books and journals, a lower level of actual and reported knowledge was indicated. Interestingly, those with no training at all, had a moderate level of actual knowledge.

Research experience was associated with higher levels of both actual and reported knowledge, whereas academic level only correlated positively with actual knowledge of ethics. This suggests that experience in research is more likely to expose researchers to research ethics issues.

There was a significant difference in the reported knowledge between doctors and other staff members with doctors reportedly knowing more regarding bioethics. Analysis of data did not reveal any pairwise differences between the occupations for actual knowledge. The results also indicated that age did not significantly correlate with either actual or reported knowledge on research ethics. This may indicate a potential bias in the recruited sample as it was expected that older faculty would have more knowledge regarding ethics than younger staff as it is assumed that they would have more experience and exposure to ethical situations.

5 CONCLUSION

5.1. LIMITATIONS AND RECOMMENDATIONS

This study is one of the first in South Africa to assess the familiarity of research ethics among healthcare professionals.

One of the limitations of this study was an underrepresentation of the population of the staff at the institution. Senior staff and those with research experience were less represented in the sample. Furthermore, the study was limited to one institution and was a convenience sample, which minimises the generalisability of the results. Moreover, the questionnaire was adapted and modified from previous studies conducted in other countries and settings. Therefore, the questionnaire may have included questions not suitable for the South African study sample.

It is recommended that further studies with larger and more representative samples be conducted from a variety of institutions, in order to improve the generalizability of findings.

The results of this study can be used to inform future curricula in research ethics in undergraduate and postgraduate healthcare education.

5.2. CONCLUSION

The knowledge and awareness of the principles and guidelines of ethics is essential for the conduct and practice of an ethical research. It is common for health care professionals to face challenges related to ethical issues. Despite the variation in knowledge between different categories of health care professionals, gaps in the knowledge of ethics have been identified amongst all categories of staff including doctors, nurses. This can be attributed to the lack of ethics education in the undergraduate curricula and postgraduate training programs.

Although the instrument used in this study was not an ideal tool, the questionnaire was designed in such a way to assess the familiarity and awareness of participants towards common set of ethics codes and guidelines.

Although the perception and awareness of research ethics was evaluated in several studies, the results were diverse with respect to the level of knowledge of ethics. Our finding showed that there is a wide variation in knowledge among health care professionals. The sources of knowledge were also varied; seminars, workshops and conferences were the preferred sources of ethics knowledge. Some of the important aspects of research ethics where knowledge is lacking include informed consent, research ethics committee and guidelines.

Further studies with an expanded sample and involvement of student, faculty and academic staff are needed. Such studies can be used to validate the results of this study and should assist to ascertain regulations and guidelines for better teaching of ethics in South Africa.

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Appendix 1

health
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To:	**Dr. O. El Koha** **Oncology Department – Grey's Hospital**
From:	**Dr. K. B. Bilenge** **CEO - Greys Hospital**
Date:	**7 December 2015**
Re:	**Request for permission to conduct research at Grey's Hospital:** ***Knowledge and perceptions of health research ethics among health care professionals at Grey's Hospital, Pietermaritzburg, South Africa***

Dear Dr. El Koha

Your request to conduct research at Grey's Hospital refers.
Permission to conduct the above study is hereby granted under the following conditions:

- Your provisional ethics approval and research protocol are assumed to be valid and final ethics approval is a prerequisite for conducting your study at our hospital. Once obtained, please submit a copy of the full ethics approval;
- You are also required to obtain approval for your study from the Provincial Department of Health KZN Health Research Unit prior to commencing your study at Grey's Hospital. You will find more information on their website: *http://www.kznhealth.gov.za/hrkm.htm*
- Confidentiality of hospital information, including staff and patient medical and/or contact information, must be kept at all times; Patient records are **not** to be removed from the hospital premises nor are you allowed to photocopy/ photograph them.
- You are to ensure that your data collection process will not interfere with the routine services at the hospital;
- You are to ensure that hospital resources are not used to manage your data collection, e.g. hospital staff collating data; photocopying; telephone; facsimile, etc.;
- Informed consent is to be obtained from all participants in your study, if applicable;
- Policies, guidelines and protocols of the Department of Health and Grey's Hospital must be adhered to at all times;
- Professional attitude and behaviour whilst dealing with research participants must be exhibited;
- The Department of Health, hospital and its staff will not be held responsible for any negative incidents and/or consequences, including injuries and illnesses that may be contracted on site, litigation matters, etc. that may arise as a result of your study or your presence on site;
- You are required to submit to this office a summary of study findings upon completion of your research.

Recommended by:

Dr L. Naidoo
Senior Manager: Medical Services

Approved by:

Dr. K. B. Bilenge
Hospital CEO

Appendix 2

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

330 Langalibalele street,
Private Bag X9051 PMB, 3200
Tel: 033 395 2805/3189/3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:
Health Research & Knowledge Management (HKRM)

Reference: **HRKM368/15**
KZ_2015RP47_25

18 December 2015

Dear Dr O El-Koha
(University of KwaZulu-Natal)

Subject: Approval of a Research Proposal

1. The research proposal titled **'Knowledge and perceptions of health research ethics among health care professionals at Greys hospital, Pietermaritzburg, South Africa'** was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

   The proposal is hereby **approved** for research to be undertaken at Greys Hospital.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee
Date: 18/12/15

Fighting Disease, Fighting Poverty, Giving Hope

Appendix 3

UNIVERSITY OF KWAZULU-NATAL

Questionnaire

Knowledge and perception of research and medical ethics among health care professionals

Thank you for agreeing to participate in this study. This is a survey based study aimed to explore familiarity and awareness of codes and regulations related to the conduct and practice of ethical research among health care professionals. This questionnaire consists of 20 items. Please take a few moments to complete each question by selecting one response and indicating your choice by an **X**.

Participation in this study is voluntary and not associated with any negative outcomes on participants. Your participation will be appreciated. No names are required for this questionnaire therefore, anonymity and confidentiality is ensured.

Please select one response

1. **What is your Occupation?**

a.	Doctor: Consultant	□	Registrar	□
	Medical officer	□		
b.	Nurse	□		
c.	Radiographer	□		
d.	Lab technician	□		
e.	Medical technologist	□		
f.	Dietician	□		
g.	Social worker	□		
h.	Physiotherapist	□		
i.	Psychologist	□		
j.	Other	□		

2. **Academic level**

Professor	□	Lecturer	□	Researcher □
none	□			

3. Age

18–25 □ 26–30 □ 31–40 □ 41–50 □ 51–60 □ >60 □

4. Gender

Male □ Female □

5. Duration of work experience

<5 □ 6–10 □ 11–15 □ 16–20 □ 21–25 □ >25 □

6. <u>What research experience have you had?</u>

A. No previous research experience □
B. I have completed research exercises at an undergraduate level □
C. I have completed a postgraduate research project/ dissertation/ thesis □
D. I have worked as an active member of research team □
E. I have led research projects □

7. Hippocratic oath

I have taken the oath Yes □ No □
I know the main contents of the oath Yes □ No □

8. How well do you know the following Ethics guidelines?

Nuremberg code Very Well □ Well □ Little □ Not at all □

Belmont report Very Well □ Well □ Little □ Not at all □

Helsinki declaration Very Well □ Well □ Little □ Not at all □

Institutional review boards Very Well □ Well □ Little □ Not at all □

CIOMS guidelines Very Well □ Well □ Little □ Not at all □

WHO guidelines Very Well □ Well □ Little □ Not at all □

SA department of health 2015 Very Well □ Well □ Little □ Not at all □

9. Regarding institutional ethics committee (IEC)

Are you aware of IEC in your institution Yes □ No □

Do you think IEC of your institution is fulfilling its role Yes □ No □

Are you aware of the composition of your IEC Yes □ No □

Could non-medical be a member of your IEC Yes □ No □

Do all studies involving human participants need to be reviewed by IEC Yes □ No □

10. What are the four elements of informed consent?

A……

B……

C……

D……

11. How aware are you of the ethical concepts of coercion and inducement?

Very Well □ Well □ Little □ Not at all □

12. What has been the Source of your knowledge of biomedical/research ethics

	Yes/No	Duration
Degree ,Diploma, Certificate Training in ethics		
Conferences / symposiums/workshops		
Short course /workshop on ethics		
In-service training on ethics		
Read Books/journals		
Online certificates		
Not at all		

If you attended course, workshops, conferences. Please give details

13. The ethical conduct of research is important because

It helps to avoid legal actions Yes □ No □
It helps to protect research participants Yes □ No □

14. Name the main ethical challenges you have faced in your clinical / research practice

……
……
……
……
……

15. Whom do you consult should you face ethical problems?

Colleague	
Supervisor	
Head of Department	
Hospital administrator	
Ethics committee	
Professional association	
Internet, Books	
Medical Protection Society	

16. Do you feel there is sufficient knowledge of ethics among health workers? Yes □ No□

17. How long should research data be stored?

……..

18. Which of the following are NOT generally considered to be vulnerable participants in need of special protections in research?

Prisoners	Yes	No
Women of child-bearing potential	Yes	No
Children	Yes	No
Mentally ill	Yes	No
Pregnant women	Yes	No
Elderly	Yes	No

19. Are you familiar with the concept of research misconduct collectively known as "FFP'' Yes □ No □

20. Do you feel the need for lectures, workshops, conferences to improve knowledge of ethics?

Yes □

No □

Thank you for your assistance and time taken in completing this questionnaire. For any queries, regarding the study or if you interested in the results of this survey please contact: **Dr Omran El-koha (**omran.elkoha@gmail.com **).**

Appendix 4

23 December 2015

Dr I El-koha
Discipline of Oncology
School Clinical Medicine
omran.elkoha@gmail.com

Dear Dr El-koha

Protocol: Knowledge and perceptions of health research ethics among health care professionals at Grey's hospital.
Degree: Non-degree
BREC reference number: BE473/15

EXPEDITED APPLICATION

The Biomedical Research Ethics Committee has considered and noted your application received on 13 November 2015.

The study was provisionally approved pending appropriate responses to queries raised. Your responses received on 18 November 2015 to queries raised on 02 December 2015 have been noted and approved by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given **full ethics approval.**

This approval is valid for one year from **23 December 2015.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its meeting taking place on **09 February 2016.**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor J Tsoka-Gwegweni
Chair: Biomedical Research Ethics Committee

Biomedical Research Ethics Committee
Professor J Tsoka-Gwegweni (Chair)
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Telephone: +27 (0) 31 260 2486 **Facsimile:** +27 (0) 31 260 4609 **Email:** brec@ukzn.ac.za
Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

Appendix 5

Knowledge and perceptions of health research ethics among health care professionals at Greys hospital, Pietermaritzburg, South Africa

INFORMED CONSENT FORM

Dear colleague

I am Omran El-koha from the department of Oncology of Greys hospital. I am conducting a study about the knowledge of heath research ethics among health care professionals working at Greys hospital and other UKZN linked hospitals

What is the purpose of this study?

The study is questionnaire based and aims to explore the familiarity and practice of heath research ethics among doctors, nurses and other healthcare professionals at Greys hospital and other health research facilities to the University of KwaZulu-Natal.

The study aims to make recommendations to improve and strengthen research ethics knowledge among health care professionals

Why have you been invited to participate?

You are invited to participate because you may have experience in the conduct of research in health facilities in KZN and your contribution will enrich the results of this study.

This study will invite a variety of representatives from greys hospital and other academic institutions in KZN, amongst other stakeholders.

What will the research involve?

You will be asked to complete a questionnaire consisting of 20 items, you will be asked questions about your experiences of the entire research process as it relates to studies conducted in health facilities in KZN. Once completed the questionnaire should be returned. This should take about 15 minutes.

Do you have to participate?

Participation is voluntary. We hope that you will give your time to complete the questionnaire, so that your views can contribute to this process.

However, you are free to decline. If you decline, this will not be held against you or your organisation/facility in any way. You may withdraw from the questionnaire at any time and you can skip the questions you don't want to answer.

Confidentiality

You name is not required to complete the questionnaire .Your completed questionnaire will be assigned a unique number.

Your anonymized questionnaire will be kept in a separate location from your signed consent form. Your name will not appear in any reports, presentations or publications that emanate from this study.

All data will be stored in a controlled access locked drawer. Electronic data (such as electronic transcripts) will be stored password protected.

What are the benefits of this study?

Whilst you may not personally benefit directly from this study, it is hoped that the results will be used to improve the research ethics education in the UKZN

Reimbursement

There will be no incentives to participate in this study as there are no expenses incurred by participants

What will happen to the results of this study?

The results of this study will be written up for a thesis as part of a degree at the University of KwaZulu-Natal. They may be submitted for publication in a peer reviewed journal. Results can also be presented to interested participants. The findings of the study will hopefully contribute to developing future resources on bioethics for health workers.

Should you have questions about this research, please contact Omran El-koha at 033 –897 3222 or omran.elkoha@gmail.com. My supervisor can also be contacted – Prof Graham Lindegger at the School of Applied Human Science, UKZN – Lindegger@ukzn.ac.za.

I understand what my involvement in the study means and I voluntarily agree to participate. I have been given an opportunity to ask any questions that I might have about participation in the study.

RESEARCH OFFICE CONTACT DETAILS: Biomedical Research Ethics Administration, Westville Campus, Govan Mbeki Building, Private Bag X 54001, Durban, 4000, KwaZulu-Natal, South Africa; Tel: +27 31 2602486; Fax: +27 31 2604609; Email: BREC@ukzn.ac.za ;

Website:http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

Declaration

I, _____ (full names of participant) confirm that I understand this consent form and the nature of the study and agree to participate

I understand that I can withdraw from the study at any time.

SIGNATURE OF PARTICIPANT

_____

DATE

_____