

A nurses' guide to ethical considerations and the process for ethical approval of nursing research

AUTHOR

Rebecca (Becky) Ingham-Broomfield, J.P.

RN (NSW), ENB249 Cardio-Thoracic Nursing (London), Cert.Ed,
Dip.Nurs. (London), BSc. (Hons), MSc (Health Psychology)
Casual Lecturer in Nursing
Armidale Rural Referral Hospital, Armidale, NSW, Australia
beckybroomfield2011@gmail.com

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ABSTRACT

Objective

A sound knowledge of the ethical principles that guide nursing practice and research are essential for any researcher. This article provides discussion regarding the principles as well as the history behind ethical practice in the construction of nursing research. The article also breaks down the process for achieving ethical consent and includes a simplified framework to guide the process of seeking ethical approval.

Primary Argument

Nurses new to the field of conducting research may benefit from an organised structure that helps them understand the sequence of events required to gain appropriate ethical approval and ensure an ethical approach is adopted. It is crucial for all researching nurses to understand, and adhere to, already well developed nationally and globally prescribed ethical and validated research study structures to be able to achieve ethical, valid and reliable research outcomes.

Conclusion

A framework is provided within this article to outline the process of gaining ethical consent for research. The information presented in the framework is based upon the discussion within the article and may assist the nurse researcher, who is unfamiliar with the process of obtaining ethics committee consent, to plan and prepare for their research approval, in a systematic logical manner. The framework reflects the National Health and Medical Research Council (NHMRC) criteria which guides Human Research Ethics Committees (HRECs). Nursing research needs to be able to ethically contribute to the body of Evidence Based Practice.

INTRODUCTION

There are two main areas to consider regarding ethics in nursing research. Firstly, there are the principles that guide the day-to-day practice of nurses (Stephens and Brighton 2015; Nursing and Midwifery Board of Australia 2013) and secondly, the important components to remember when conducting research. This paper will therefore define and apply the six ethical principles relevant to health professionals (Lumby 2016; Stephens and Brighton 2015), discuss the historical background that underpins the relevance of adhering to codes of ethics and conduct, particularly when researching human participants (Johnstone 2016), and lastly, provide an overview of the steps required to ethically undertake nursing research and gain ethical consent from the appropriate committees.

ETHICS, ETHICAL PRINCIPLES AND ETHICAL CONSENT FOR UNDERTAKING RESEARCH

Ethics refers to the moral principles that guide decision-making and behaviour (Stephens and Brighton 2015) or how to best live a life which is moral (Johnstone 2016). Harris et al (2014) further clarify the definition of ethics as the rules and standards by which a community regulates the behaviour of its members. Moral principles, therefore, arise from beliefs about what can be considered right or wrong, which may be socially, professionally or philosophically based (Stephens and Brighton 2015). Johnstone (2016) states there is no philosophically significant difference between the terms *ethics* and *morality* which can be used interchangeably however, Atkins et al (2014, p26) disagree, believing ethics differ from morals stating that moral principles are rule-like expectations or beliefs that a person considers to be ethical. Ultimately, the main message for nurses and nurse researchers is to live, work and research ethically and to follow a “good life” from which all humans can flourish physically, emotionally, psychologically, morally, interpersonally and socially (Atkins et al, 2014, p24).

The Nursing and Midwifery Board of Australia (NMBA) (2013) has a Code of Ethics by which all nurses should abide whether practising within a hospital setting, an educational institution or whilst undertaking any research to protect the moral interests and welfare of patients (Adrian and Chiarella 2016; Johnstone and Crock 2016) and act as advocate (Epstein and Turner 2015; NMBA 2013). If a researcher is specifically undertaking human research it falls under the label of Bioethics (Stephens and Brighton 2015) which is derived from the Greek *bios* meaning life (Johnstone 2016). Bioethics refers specifically to ethics that are applied to human life or health decisions (Johnstone 2016).

Ethical consent to undertake research is given by appropriate ethics committees. As one example of ensuring researchers, pursuing publication, have adhered to National and Global ethical standards, the British Medical Journal (2017) require every research article submitted to *The BMJ* to include a statement that the study obtained ethics approval (or a statement that it was not required), including the name of the ethics committee(s) or institutional review board(s), the number/ID of the approval(s), and a statement that participants gave informed consent before taking part. In addition they welcome detailed explanations of how investigators and authors have considered and justified the ethical and moral basis of their work. Hand in hand with this is the necessity to ensure that ethical principles are acknowledged within any research undertaken as discussed below. Through rigorous procedures following ethical standards both professions show a high commitment to quality and safety (Arries 2014).

Medical practice is guided by the Hippocratic Oath (Harris et al 2014) whilst nursing practice follows six main bioethical principles that underpin professional behaviour (NHS Scotland 2017; Lumby 2016; Stephens and Brighton 2015). Firstly, *autonomy* refers to the right for a person to make their own decisions (Stephens and Brighton 2015) which basically means that people should be respected as self – determining choosers

(Johnstone and Crock 2016) and be free to act upon their preferences (Johnstone 2016). This also applies to any person who is the subject of research. Every potential subject has the right to be fully informed and the right to refuse participation (Jirojwong et al 2013; 2014). Hand in hand with this is the principle of *justice*, broadly defined or known as, fairness (Johnstone 2016; Stephens and Brighton 2015). Whether patient or research subject, the nurse or nurse researcher, needs to weigh up and prioritise but remain as fair as possible. A component of the principle of justice is the subjects right to fair treatment and equal opportunity (Johnstone 2016). Specifically, there is a right to privacy which means that, both in nursing practice and whilst undertaking research, confidentiality should be afforded to each patient or subject (NMBA 2013).

With any research, ensuring the principle of *non-maleficence*, or to do no harm, is paramount (Johnstone and Crock 2016; Stephens and Brighton 2015) which entails a stringent obligation not to injure others (Johnstone 2016). Florence Nightingale, in her Notes on Nursing, stated the first duty of a hospital “is to do the sick no harm” (Robb 2014). Research in to human subjects should, therefore, have the ultimate intention of *beneficence*, defined simply “to do good” (Johnstone and Crock 2016; Stephens and Brighton 2015, p95; Perrin 2014) which entails a positive obligation to act for the benefit of others (Johnstone 2016). This specifically entails that the research ensures the subjects have freedom from harm, freedom from coercion and the risk of exploitation is avoided (Perrin 2014). The researcher should weigh up the risk to benefit ratio. There needs to be clear understanding of the risks and benefits that may be incurred in a study.

The remaining two principles are *fidelity* and *veracity*. Fidelity is to be faithful to agreements and promises (Stephens and Brighton 2015) which links strongly to ensuring the patient, or subject, remains autonomous and fully informed. Veracity refers to telling the truth (Stephens and Brighton 2015). The ethical nurse, or nurse researcher, is able to explain the rationale behind every action and recognises standards to be upheld. As nurses are accountable for their actions it is essential that these principles are understood and the research process follows accordingly (Adrian and Chiarella 2016; NMBA 2013;).

HISTORICAL BACKGROUND

Nursing codes for professional practice and ethics have been developed over the years to protect both the nurse and the patient or client. Codes underpin morality and consequently permission from an ethics committee is a pre-requisite to carrying out any research on human subjects (Liamputtong 2013). This requirement has been established due to a long and harrowing background of unethical behaviour and research that serves to highlight the enormous relevance and importance of human consent (Slowther et al 2006).

One of the most notorious examples of unethical medical research was carried out during the Second World War (WWII) in Germany by Dr. Josef Mengele, who became known as the Angel of Death (United States Holocaust Memorial Museum 2016; Cefrey 2001) or the ‘White Angel’ because of his coldly cruel demeanour (United States Holocaust Memorial Museum 2016). His experiments became infamous because of his interest in experimenting on twins (Cefrey 2001, p11). It is known that 1,500 pairs of twins were subjected to immoral research (Liamputtong 2013). Mengele’s practice included injecting dye in to the eyes of the twins in a bid to change their colour (United States Holocaust Memorial Museum 2016). This was an attempt to ensure the future of the Aryan race desired by Hitler – tall, blonde with blue eyes (United States Holocaust Memorial Museum 2016). Twin research was seen as an ideal tool in weighing the variant factors of human heredity and environment. Mengele, with his mentor, had performed a number of legitimate research protocols using twins as test subjects throughout the 1930s. Now, at Auschwitz, with full license to maim or kill his subjects, Mengele performed a broad range of agonising and often lethal experiments with Jewish and Roma (‘Gypsy’) twins, most of them children (United States Holocaust Memorial Museum 2016).

Following WWII many members of the Nazi regime were brought to trial however Mengele managed to escape (Cefrey 2001). The Nuremberg Trials commenced in December 1946 (Jirojwong et al 2013), lasting until 1949, in response to the Nazi experimentation on innocent people who did not consent to participation in atrocious experiments during the Third Reich/Nazi regime (Jirojwong et al 2013; Slowther et al 2006). From the trials came the seven Nuremberg Principles which now form the bedrock of modern international criminal law and justice (International Nuremberg Principles Academy 2016). The formation of the principles led to the Nuremberg Code to control future trials involving human subjects, a set of research ethics principles for human experimentation. There are ten specific points in the Nuremberg Code that serve as a standard against which to measure individuals rights when participating in experimental and clinical research. The first point specifies the voluntary consent of human beings is absolutely essential (United States Holocaust Memorial Museum 2016). The fourth point is significant in that it asserts any experiment should avoid all unnecessary physical and mental suffering and injury (United States Holocaust Memorial Museum 2016).

Following the Nuremberg Code came the Declaration of Geneva (1948), a revision of the Hippocratic oath, which states "A physician shall act in the patient's best interest when providing medical care". The World Medical Association (WMA) developed the Declaration of Helsinki, which was adopted by the 18th WMA General Assembly in Helsinki in Finland, in June 1964 (WMA 2016). It contains 37 basic aims and principles for human research including research on identifiable human material and data (WMA 2016). The contents of the Nuremberg Code, and following declarations have, over the years, been filtered through to every profession to accept the responsibility of a Code of Ethics.

However, despite the promise of ethical behaviour in research, trials still went ahead which were immoral and unjust. There are many known unethical research studies which have left the non-consenting participants damaged beyond repair or dead (Brandt 2012). Disrespect for human life and paternalism are clearly evident in the following example of immoral research, namely the USA Government Tuskegee Syphilis Study. Paternalism by definition is where there is a relationship of uneven power between the recruiter and the individuals being recruited (Perrin 2014). The Tuskegee Syphilis Study was held between 1932-1972 and investigated the effect of syphilis on approximately 399 poor African Americans plus 201 as a control group (Perrin 2014; Liamputtong 2013; Brandt 2012). The men were never told they were in a research study and did not receive proper medical care to treat the syphilis (Perrin 2014). Treatment was deliberately withheld to study the course of the untreated disease despite penicillin having been found to be the cure in 1947 (Liamputtong 2013) and widely available in the 1950's (Brandt 2012). By the end of the study only 74 were alive, 28 had died directly of syphilis, a 100 due to related complications, 40 wives were infected and 19 children had been born with congenital syphilis (Perrin 2014). On 16 May 1997, after 65 years, President Clinton apologised for the USA Government's syphilis study in Tuskegee but the lack of respect for autonomy and indifference to informed consent left a legacy of mistrust (Perrin 2014).

Another later example of unethical behaviour is the prescribing and use of the medication Thalidomide. Thalidomide was marketed in the late 1950's as a wonder drug – a tranquiliser, pain killer, used for insomnia, coughs and headaches (Hajar 2011). It was given to pregnant women to help with morning sickness and was considered safe however more than 10,000 children in 46 countries were born with malformations or missing limbs (Woodruff Library 2016; Hajar 2011). No animal studies had been conducted to investigate the safety of Thalidomide on the unborn child (Hajar 2011). Many of the victims of Thalidomide did not survive more than a year. Later, Thalidomide underwent rigorous testing. On 26 May 2006, the U.S. Food and Drug Administration (USFDA) granted accelerated approval for Thalidomide (Thalomid), in combination with dexamethasone for the treatment of newly diagnosed patients with multiple myeloma (MM) (USFDA 2015). Thalidomide has also been found to reduce multiple symptoms commonly associated with cancer-related anorexia and improved quality of life (Davis et al 2012).

Given this background, it is essential, when choosing your topic, the nurse researcher needs to consider vulnerable subjects such as the elderly, children, people who are mentally, physically or emotionally disabled, people who are institutionalised, pregnant women or anyone in a position of limited power or input (Johnstone and Crock 2016; NMBA 2013). The nurse and nurse researcher can play a significant ethical role in supporting the person's trust and ensuring they are unharmed and their vulnerability is not further undermined (Atkins et al 2014; Slowther et al 2006). This has long been acknowledged as an important component of nursing and nursing research.

Nurse educators in the late 1980's such as Leino-Kilpi and Tuomaala (1989) noted scientists and scholars were paying more attention to the problems of research ethics. They stated two key questions in data collection were the accuracy with which the research design was followed and the treatment of the subjects who were the sources of information. The authors noted the most important requirement in the publication of research results is the necessity for honesty (Leino-Kilpi and Tuomaala 1989). Some years prior to their observations Sheehan (1985, p336) discussed that honesty is basic to all human relationships and whilst there may be conflicting interests, potential conflict and tension in both nursing practice and research, nursing in all its guises must be able to fundamentally sustain constant reflection and eternal vigilance to ensure moral integrity. This observation also applies to the storage of data ensuring patient confidentiality and protection from unwanted public viewing and hacking. When a nurse chooses to research they must make a moral commitment to care for all patients (Lachman 2012).

APPROACHING AN ETHICS COMMITTEE

The role of Human Research Ethics Committees (HREC's) is to make fair and just decisions to protect human subjects (Liamputtong 2013). Historically, in Australia, the Medical Council issued a statement in 1966 in a direct response to Helsinki, to make it a requirement that all proposed research involving human subjects be examined by an institutional ethics committee (Liamputtong 2013, p28). By 1985, human research without permission from an appropriate ethics committee could not be provided with public funding. This was followed by the establishment of The National Health and Medical Research Council (NHMRC) in 1992 which has established further guidelines including that an ethics committee be made up of research, health and social care professionals, a lawyer, lay members and someone from the pastoral community (Liamputtong 2013, p28; Hunter New England Local Health District 2016). Ethics Committees within hospitals have levels of research requiring different reviews from a HREC from low and negligible risk (LNR) to non-research activity which may simply be a presentation on medical procedures (Hunter New England Local Health District 2016).

There are more than 200 HRECs in institutions and organisations across Australia. They play a central role in the Australian system as they review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. In undertaking this role, HRECs are guided by relevant standards. Standards include those outlined in the National Statement on Ethical Conduct in Human Research issued by NHMRC. Researchers, Institutions and Human Research Ethics Committees (HRECs) are advised to use the NHMRC web site to ensure they are accessing the current version of the National Statement, and to check regularly for updates (NHMRC 2017). They also provide access to the appropriate forms for ethical consent of a research proposal as outlined in table 1.

CONCLUSION

Every nurse and nurse researcher has a duty to ensure they uphold the ethical principles to safeguard their patients (NMBA 2013). An appreciation of the history behind the development of codes of conduct and ethics can only reinforce the importance of ensuring patient safety when undertaking research. Following appropriate

guidelines and making certain the correct avenues are followed for gaining ethical research consent and permission will aid in protecting participants and researchers from inappropriate research. The framework below has been designed to simplify the process of gaining appropriate ethical consent to undertake research.

Table 1: Ethical considerations and the process for ethical approval of nursing research

Choosing your topic	What are the ethical implications of the topic for research? Think about power relationships and patient vulnerability. How will you ensure your participants are protected from harm? Consider the six ethical principles and how they are addressed in your research.
Choosing your research design	Will it be qualitative or quantitative? Think about how you will gain consent? Depending on the design this may be done electronically, face to face or through mail drop. How will you maintain privacy, anonymity and confidentiality? Think about your sample of respondents and their specific cultural, religious and language needs.
Approaching an ethics committee	This depends on your research topic and audience. You may need to approach a university ethics committee or a hospital based one. Find out from your supervisors who you need to approach.
Ethics forms and approaching your participants	The NHMRC (2017) provides information on Human Research Ethics Application (HREA) Resources at https://www.nhmrc.gov.au/health-ethics/human-research-ethics-application-hrea . Researchers of all disciplines can complete forms available on the website for submission to the appropriate HREC. Universities and hospitals are the most likely to have a Human Research Ethics Committee (NHMRC 2017). You will be asked to use the Human Research Ethics Application found at https://hrea.gov.au/ with a support site found at https://www.nhmrc.gov.au/health-ethics/human-research-ethics-application-hrea/hrea-support ? The Aboriginal Health and Medical Research Council of NSW (2017) operates as a HREC to assess research proposals affecting the health and wellbeing of Aboriginal people and communities in NSW. You can find this information if you follow the link: http://www.ahmrc.org.au/ethics.html Standardised participant and information consent forms can be accessed from NHMRC at https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/standardised-participant-information and hospital based HRECs, such as NSW Health (2017) have online information, found on the Intranet http://www.health.nsw.gov.au/ethics/Pages/contacts-hrecs.aspx including Participant Consent Forms. Other specific districts, such as Sydney Local Health District, have websites explaining how to access information from their Research Ethics and Governance Office http://www.slhd.nsw.gov.au/RPA/Research/
Storage of data	Where will you store your data? Think how you can keep it safe from public viewing or potential hacking. Is it safe, secure and backed-up? Will you be able to access it in 1 year, 2 years, 5 years? How will you ensure you remember the specifics of the data? Can it be made available for archiving, discovery, and possible publication or reuse?

(Aboriginal Health and Medical Research Council of NSW 2017; Hunter New England Local Health District 2017; NHMRC 2017; Deakin University 2015; Jirojwong et al 2014; 2013).

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