

ETHICAL CONDUCT IN RESEARCH

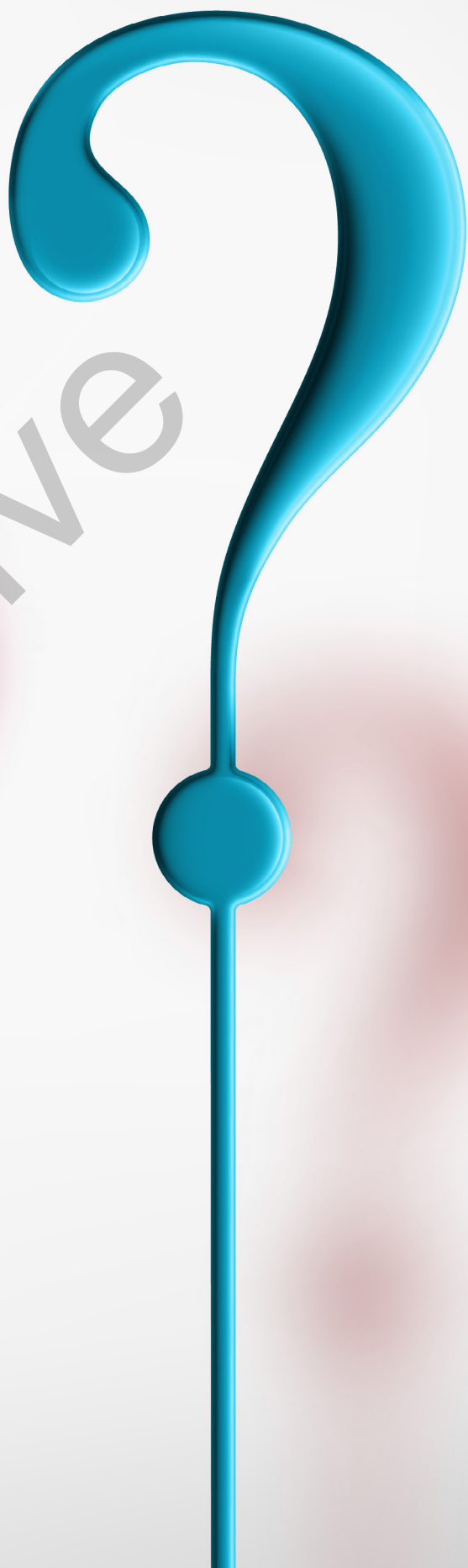
Professional guidance



Bord Altranais agus
Cnáimhseachais na hÉireann

Nursing and Midwifery Board
of Ireland

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This professional guidance was originally published in January 2007 as *Guidance to Nurses and Midwives Regarding Ethical Conduct of Nursing and Midwifery Research* (First Edition).

This document was re-issued in November 2015 for the relaunch of the NMBI website. This involved reviewing the content for updating dated NMBI references and redesigning the document. However, the content reflects what is in the 2007 edition.

About NMBI

The Nursing and Midwifery Board of Ireland (NMBI) is the independent, statutory organisation which regulates the nursing and midwifery professions in Ireland. For more information about our role and functions, visit www.NMBI.ie/What-We-Do

Glossary

A full glossary of all the terms used in this and other NMBI publications is published on our website on www.NMBI.ie/Standards-Guidance/Glossary

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INTRODUCTION

The Research Strategy for Nursing and Midwifery in Ireland (Department of Health and Children, 2003), charged NMBI (formerly An Bord Altranais) with developing a position statement concerning ethical conduct of nursing and midwifery research. Following consultation with a range of nurses and midwives, the Ethics Committee developed this guidance document. Its purpose is to provide nurses and midwives with general guidance on ethical matters relating to research and to ensure the protection of the rights of all those involved in research.

This guidance document is for use by registered nurses and midwives who are:

- In clinical practice and who may be caring for patients and clients who are participants in research
- Involved in research as research assistants, research nurses/midwives or who are collecting data for a research team
- The lead researchers of research projects, including masters or doctoral students undertaking research
- Clinical staff, managers and administrators responsible for patients, clients and staff and who are involved in reading, interpreting and using research as a basis for practice
- Members of ethics committees who are involved in reviewing research proposals
- Educators with responsibility for teaching and supervising research projects.

Nursing and Midwifery Research

It is widely acknowledged that scientific research is central to the development of nursing and midwifery as professional disciplines and to ensuring that they provide the highest quality and most cost-effective services to society. Nursing and midwifery research may be described as systematic scientific inquiry conducted to develop knowledge for the profession, and includes clinical practice, management, education and informatics. The definition of research used in the Research Strategy for Nursing and Midwifery is as follows:

The process of answering questions and/or exploring phenomena using scientific methods; these methods may draw on the whole spectrum of systematic and critical inquiry (p.16).

As practice disciplines, nursing and midwifery are particularly concerned with developing knowledge to guide practice and to improve the health and well-being of those they serve (Polit and Beck 2004). Nursing and midwifery research also encompasses the use of research findings to guide practice and is a significant component of evidence-based practice.

THE CODE OF PROFESSIONAL CONDUCT AND ETHICS FOR REGISTERED NURSES AND REGISTERED MIDWIVES

Professional nurses and midwives are required to develop scientific knowledge which guides their practice; therefore, a commitment to research is essential. The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (NMBI, 2014) Principle 3 Quality of Practice focuses on the professions' role for research.

"Nurses and midwives use evidence-based knowledge and apply best practice standards in their work.

Nurses and midwives value research. Research is central to the nursing and midwifery professions. Research informs standards of care and ensures that both professions provide the highest quality and most cost-effective services to society.

You should deliver safe and competent practice based on best available evidence and best practice standards." (pages 20-21).

Health care organisations have a responsibility to ensure that policies and procedures are in place to guide those involved in all aspects of research. In addition, nurses and midwives are encouraged to use the findings of research. The Code gives reference to this by stating:

“ You should deliver safe and competent practice based on best available evidence and best practice standards ”

Nurses and midwives must be familiar with and understand the importance of Board's most current version of standards and guideline documents and should apply them in any professional settings. These include:

- The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives
- Practice Standards for Midwives
- Scope of Nursing and Midwifery Practice Framework
- Recording Clinical Practice, Guidance to Nurses and Midwives

The principles underpinning the scope of nursing and midwifery practice include respecting the dignity and rights of patients, promoting and maintaining patient safety, providing quality care, facilitating patient autonomy, informed choice and evidence-based decision-making. These principles apply equally to research activity. The Scope of Practice framework is also relevant to the nurse's or midwife's role in research. The framework takes cognisance of the overall benefit to the patient, legislation, local national, and international evidence-based clinical practice guidelines/policies and the concepts of responsibility, accountability and autonomy, and competency.

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ETHICAL PRINCIPLES

Good ethical conduct implies adherence to ethical standards. In undertaking research, certain ethical principles are used as a framework to guide the researcher through the research process and its subsequent use. These principles help to ensure the highest possible standards in every aspect of research and must be adhered to by nurses and midwives. The ethical principles have been identified by many authors in the professional literature and include respect for persons/autonomy, beneficence, non-maleficence, justice/fairness, veracity, fidelity and confidentiality (ICN, 1996, Beauchamp and Childress, 2001, Polit and Beck, 2004, Storch et al, 2004).

Respect for Persons/Autonomy

Respect for autonomy considers the individual as an independent person who is able to make choices for him/herself (Rogero-Anaya 1994). Within the research context, the researcher is required to make certain that the principle of autonomy is adhered to for those participating in healthcare research by ensuring:

- The right to self-determination, which means that a person has the right to choose whether or not to participate in a research study
- The right to full disclosure, ensuring that a person has received information outlining the nature of the study, including the likely risks and benefits, allowing them to make an informed choice
- The participant has the right to withdraw at any time with no consequences.

The right to self-determination and the right to full disclosure are major components on which informed consent is based (Burns and Grove, 1999, Polit and Beck, 2004).

For some groups in society, it may not always be possible to assure the principle of respect for autonomy (O'Neill, 1977). Some may have diminished levels of autonomy and need additional protection regarding participation in research studies, because of their inability to give true informed consent.

Beneficence and Non-maleficence

Beneficence means "to do good" and positively help a person, and non-maleficence means "to do no harm". Research should benefit client/patient participants and contribute to their welfare (Treacy and Hyde, 1999) and it should benefit both individual participants and society as a whole (Parahoo 1997). Participants have the right not to be harmed. Researchers have an ethical duty to balance potential benefits against potential risks and to minimise potential risk to the greatest extent possible, thus safeguarding and protecting participants.

Justice

The principle of justice is synonymous with fairness and equity and researchers are obliged to treat participants fairly and equitably before, during and after the research study.

Veracity

Veracity involves the concepts of truth about the research study and the absence of deception. Individuals have the right to be told the truth and not to be deceived about any aspect of the research. All aspects of a research project require explanation by the researcher, who must make every effort to ensure the participants understand the implications throughout the study. The principle of veracity is linked with respect for autonomy (Gillon, 1994).

Fidelity

Fidelity involves the concept of trust (ICN, 1996). Participants place trust in researchers and this necessitates a commitment to protect them. The researcher must ensure that the participants have an understanding of the risks, and thus foster a trusting relationship.

Confidentiality

The researcher is responsible for ensuring confidentiality and privacy of the research participants and the data obtained from them. Personal information obtained by the researcher must not lead to identification of research participants and this information should not be made available to others without their consent. There are exceptional circumstances where information may have to be disclosed without the permission of participants, thus breaching confidentiality. These circumstances include public interest and safety and when the researcher believes that there may be a risk in non-disclosure. The researcher must have clear justification for the disclosure of information and should seek support from the research supervisor, ethics committee and other relevant persons. The decision should be clearly documented.

Personal information obtained through group research needs vigilance from both the researcher and research participants to maintain confidentiality.

Researchers can ensure that confidentiality is maintained by assigning an identification number to each participant, so that identifying information is effectively secured and that identifying information is not entered on a computer system or other potentially accessible database. (Polit and Beck, 2004).

CONSIDERATIONS WHEN UNDERTAKING RESEARCH

Informed Consent

The purpose of informed consent is to protect research participants and allow them to make informed choices. Obtaining written informed consent to participate in research is one of the most important ethical considerations in the research process and it ensures that the principle of “respect for persons” is acknowledged and adhered to. Consent to participate in research should never be presumed. The Nuremberg Code defines informed consent (1947) as follows:

“The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.” (Boomgaarden 2003 et al, p.108).

The four essential components required for a valid informed consent are:

- a. Disclosure of information
- b. Comprehension
- c. Competency
- d. Voluntariness (Beauchamp and Childress, 2001).

a. Disclosure of Information

Participants must be fully informed of all aspects and proceedings of the research project, including the risks, benefits and the right to withdraw from the project at any time. The information provided must be sufficient, and communicated accurately in an understandable way and using appropriate language or mechanisms. With regard to the comprehension of information, the participant should be given time to consider the research so that questions can be asked of the researcher. The opportunity for participants to ask questions about the proposed research on a continuous basis is also required.

Disclosure includes:

- Aims of research
- Methodology to be used
- Anticipated risks and benefits
- Anticipated discomfort or inconvenience
- Participant's right to withdraw from the research at any time without prejudice.

b. Comprehension

The researcher must ensure that every effort has been made to ensure the participant understands the information disclosed.

c. Competence

If a person is to make a decision regarding participation in research, he/she must be competent to understand and be able to come to a decision about what is involved. Certain groups may be excluded from participating in research because they are unable to give a valid consent. Some clients who are cognitively impaired may understand simple explanations and therefore give informed consent. Clients with severe mental health problems may at times be capable of providing informed consent. Nurses and midwives at the earliest possible opportunity must seek the direction of the appropriate/relevant Ethics Committee.

Children may not be competent or able to give an informed consent and therefore the concept of assent is utilised. Assent takes into consideration the participant's rudimentary understanding of what will result from involvement in the research, the purpose of the research and their ability to decide on participation (Mitchell, 1984; Beidler and Dickey, 2001). This is in addition to the consent from a legally competent person such as a parent.

The Declaration of Helsinki (1964) implies that those who are unable to give an informed consent can participate in research. If there is another mechanism provided to obtain informed consent that research should only be carried out if it is in the best interests of the participants. In Irish law, the consent of non-capacious clients can be obtained only through the mechanisms of wardship and enduring power of attorney.

d. Voluntariness

Consent to participate must be given voluntarily and is only valid if given without intimidation (Watts, 1997), coercion, persuasion, manipulation or inducement. The researcher must ensure the right of each participant to determine his or her voluntary participation in research.

Written informed consent is required for all research. The consent form should provide a written explanation about the research study, including the purpose of the study, study design, sampling procedure and potential benefits and risks and voluntary nature of the study. A consent form is signed and dated by the research participant and the researcher. Where research involves the use of questionnaires, completion of the questionnaire implies consent is being given. This is appropriate, as it contains all the elements of informed consent.

Elements Of Informed Consent:

- Title of study
- Researcher(s) and credentials identified
- Study population identified
- Purpose of study
- Study procedures and steps for data collection described
- Potential risks described
- Potential benefits described
- Anonymity or confidentiality assured
- Assurance given that participation is voluntary
- Right to refuse to participate or withdraw at any time assured
- Offer made to answer all questions
- Means of obtaining study results provided
- If signed consent, consent form should have dated signatures of participant and researcher (Meehan, 2004).

Research Ethics Committees

It is important that research practices are continually monitored, audited and evaluated. Many healthcare services/institutions and higher education institutions utilise research ethics committees to ensure proper scrutiny of research and clinical trials. These committees have stringent standards, guidelines and policies to which researchers must adhere. Before undertaking a project, the researcher needs to be aware of the ethical considerations in relation to the research project and the particular guidelines, policies and procedures necessary to obtain approval from the healthcare services/institutions or higher education institute.

It is the responsibility of the researcher to obtain ethical approval prior to initiating a research study. When applying to ethics committees for approval, all the ethical issues must be identified clearly in the written proposal and the researcher must demonstrate how these will be addressed in the conduct of the research study. The purpose of a research ethics committee in reviewing a study is to protect the rights, dignity, well-being and safety of participants in a research study, thus ensuring that participants are protected from unethical practices. The committee is also required to ensure that the interests, needs and safety of the researcher undertaking the study are assured, but the dignity, rights and safety of the participants must not be secondary to this.

Questions Which Ethics Committee Will Consider:

- Is the study scientifically sound?
- Is there a clear indication of the type of research proposed?
- What is the rationale for the research?
- What are participant recruitment procedures, including inclusion and exclusion criteria?
- How are the well-being and safety of the participants being safeguarded?
- What facilities are in place to deal with unexpected physical, psychological and emotional consequences resulting from the research process?
- What procedures are in place to obtain informed consent, including consent form?
- Will the research be adequately supervised by an experienced researcher who is sensitive to the ethical issues involved?
- Will the researcher adhere to existing codes, policies and guidelines in relation to confidentiality, data protection and local, national and international legislation? (Tierney, 1995; National Health and Medical Research Council, 2002).

Vulnerability

Vulnerability needs consideration in relation to the research process. Individuals who are the recipients of nursing and midwifery care/intervention may be vulnerable because of patient and client status and require additional protection because of their vulnerability. Likewise children and certain groups of

adults such as unconscious patients, the terminally ill, some elderly people and those with mental health problems may be viewed as vulnerable participants. Potentially vulnerable groups should not be chosen simply because they are readily available. They may lack insight and competence to make an informed decision to participate in a research project. It is vital that the nurse and midwife, irrespective of their role in the research process, protect vulnerable individuals and respect their right to self-determination and autonomy.

Groups With Potentially Vulnerable Persons:

- Patients
- Those who are disabled, physically, intellectually, socially and emotionally
- Those who are hearing or visually impaired
- Persons who reside in institutions and residential settings
- Pregnant women
- The unborn
- Children and adolescents
- Elderly
- Prisoners
- Students
- Those whose first language is not English.

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ETHICAL CONDUCT AND THE RESEARCH PROCESS

Care must be taken to ensure that the research design is ethically rigorous. Many steps within the research process need to be considered from an ethical perspective such as sampling, data collection, data analysis, storage and disposal of data. The researcher must ensure that the sampling procedures take cognisance of ethical and research principles and take guidance from a research ethics committee. It is important that the researcher ensures that participants receive adequate knowledge about the data collection methodology and the measurement instrument(s) to be used so that they can make an informed decision and give consent to their participation in the research.

Furthermore, it is imperative that the researcher ensures that all collected information is disclosed and that data analysis is complete and not selective (Noble-Adam, 1999). Data should not be manipulated in any circumstances. Local policies and the research ethics committee will determine the storage and disposal procedures of the research data.

The role of the nurse	Ethical questions
The nurse/midwife as researcher	<ul style="list-style-type: none"> • What is the responsibility of researcher to the patient? • Is the researcher competent to undertake research?
The nurse/midwife as a research assistant	<ul style="list-style-type: none"> • Are there conflicting responsibilities because of the role of the nurse/midwife as care provider and the role of the nurse/midwife as research assistant?
The nurse/midwife as a research facilitator	<ul style="list-style-type: none"> • Is it in the best interests of the patient that research takes place in the clinical area?
The nurse/midwife as a research subject	<ul style="list-style-type: none"> • Are there conflicting responsibilities because of the role of the nurse/midwife as research subject?
The nurse/midwife as a consumer of research	<ul style="list-style-type: none"> • Have nurses/midwives a duty to update themselves and implement new knowledge?

(van der Arend, 2003)

USE OF RECORDS IN RESEARCH

When patient/client records are utilised in research, they are subject to the same ethical considerations as any other type of research. The principles of privacy, confidentiality and anonymity must be respected. Competence in research requires that confidentiality be ensured in respect of records.

In addition, the researcher must:

- Adhere to the institutional policy regarding records
- Abide by the Data Protection Acts, 1988 and 2003
- Consider the rights of patients past and present, whose records are to be utilised in research and which may involve seeking their written consent.

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CLINICAL TRIALS

Much advancement in health science and therefore the improvement of patient/client care is due to the use of clinical trials. The role of the nurse and midwife in clinical trials may involve the recruitment of participants, implementation of protocols, recording of data, and monitoring and evaluation of the results of the clinical trial. Nurses and midwives are in a key position to ensure that participants are protected at all times. Those involved in clinical trials need to be aware of the potential risks and benefits if patients in their care are to participate in clinical trials. It is important that voluntary informed consent has been obtained and documented before any trial. Those involved in clinical trials must refer to Statutory Instrument S.I. Number 190 of 2004 European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations as amended.

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SUMMARY

- All nurse/midwife researchers are required to take cognisance of the principles within the Nuremberg Code (1947), the Helsinki Declaration (1964), human rights legislation, Freedom of Information Act, 2014 and the Data Protection Acts, 1988 and 2003
- It is the responsibility of the researcher is to ensure that no harm, risk, or injury occur to the participants
- At all times, the rights and dignity of the participants must be respected. It is important to ensure that the principles of confidentiality, privacy and equity are assured
- All participants must be fully informed about the research and its implications and, if they are willing to participate, a written informed consent is required
- All participants need to be made aware of their right to withdraw at any time without any repercussion
- Nurses/midwives involved in research activities must adhere to the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (NMBI, 2014)
- Nurses, midwives and students who are research participants must be assured of their rights within the research process.

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