Royal College of Nursing

Research ethics

RCN guidance for nurses

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The RCN Research Society Ethics Guidance Group

Chair – Martin Johnson, Professor in Nursing, University of Salford and Editor, Nurse Education Today

Ian Buchanan, Bury and Rochdale Local Research Ethics Committee

Tony Long, Associate Head of Department for Nursing Research, University of Salford

Lyndsey Peacock, Senior Lecturer in Nursing Law and Ethics, University of Central Lancashire

Tracey Williamson, Nurse Consultant, Pennine Acute Services NHS Trust

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Introduction

This guidance considers the ethical issues of carrying out research with human subjects, and the areas which you as a nurse researcher, manager, student, member of a research ethics committee or any other relevant role must consider when setting up or advising on research studies. It is a guide to basic principles, and with its extensive list of Internet resources, a gateway to further information.

Nursing research has changed a great deal since the Royal College of Nursing (RCN) first published its influential guidance on research ethics for nurses in 1977. Many more nurses are now participating in research for degree programmes; nurses based in higher education are expected to be active in research; and there are more nursing roles with a research and development element, such as nurse consultant. Many nursing activities involve the collection and interpretation of information from and about patients and staff, from small-scale practice development projects to large, multi-centre clinical trials. People are also much more aware of their right to information and consultation about care, treatment and any associated research. There is, as well, a trend towards greater accountability in health care, and research is a vital part of developing the nursing evidence base.

What do we mean by 'research'? The many ways of collecting and analysing information are described in varying terms – research, evaluation, clinical audit, quality assurance or student projects – and will vary in depth and scale. The ethical issues are usually the same. While the specifics of approval for studies by research ethics committees will differ for each organisation and according to the type of investigation, this document provides general guidance for all these forms of investigation. Key sources of information are given in the text under *Further information*, with full contact details given under *References* and *Useful Internet resources*.

Your responsibilities

Nurses act in a range of roles in research – including carer, student, manager, investigator, research supervisor, sponsor, ethics or governance committee member. Whatever your role, you have clear responsibilities to patients and their families, and to colleagues, to make sure that research you are involved in, or know about, is of the highest standard. As the United Kingdom Nursing and Midwifery Council states, nurses must "act to identify and minimise the risk to patients and clients."

In most respects nurses are in the same position as other health professionals when it comes to the ethics of research – their common law obligations and accountability do not differ in principle from those of any other health profession. In ethical terms, too, nurses have no more right than any other health professional to hide behind notions of subordination, compliance and obedience to justify avoiding personal responsibility for what they do as part of a research study.

You may, however, face situations in which your professional position and status as a nurse, and the nature of your role, can present particular challenges. If you are responsible for patient or client groups involved in research, or are simply a third party who witnesses research activity, you must review how your actions, or those of others, impact on vulnerable subjects or participants. As with everything in nursing, you must put the patient first.

Further information: If you are setting up and seeking approval for a research study, the UK Central Office for Research Ethics Committees (COREC) co-ordinates policy and procedures for National Health Service (NHS) ethics committees in England and offers useful guidance on approval procedures. You must get approval from your local research ethics committee (LREC), which can provide general advice on when to apply for approval. Addresses for LRECs throughout the UK can be obtained from: COREC, Room 75-77, B Block, 40 Eastbourne Terrace, London, W2 3QR.

Ethical issues

Respect for every individual

Every individual is important, and deserves to be treated with respect. This value, which is upheld in law and supported by most philosophies, must underpin your work in research. It is important that research is done *with* respondents, rather than on them. You may have responsibility for many individuals rather than just one, and you should ensure that the rights of each individual are considered (for example, sampling should be as inclusive as possible).

In law, every human being, from the moment of birth to the point of death, is held to have interests and rights enforceable by law. The law even protects fetal welfare in some respects, even though a fetus is not recognised as a legal entity.

Where research with humans is concerned the scope of those worthy of respect and, therefore, protection is wide: everyone should be protected from undue harm, and their rights respected. When it comes to obtaining approval for research from your local research ethics committee (LREC), those whose rights must be considered will include past as well as present NHS patients, and their records (even if the individuals themselves are not involved), and those who have recently died in NHS premises. Approval will also cover the use of NHS premises, access to NHS staff, and the use of fetal material.

Autonomy

Autonomy is the ability of an individual to make reasoned decisions about issues that affect them. If we respect people, then we must also respect their autonomy, and seek to incorporate their wishes into decisions about their health care – and about their participation in health care research.

A number of factors may restrict the degree of an individual's autonomy, or their ability to exercise it. To be able to act in a truly autonomous manner a patient must:

- be able to understand the issues involved in their care, and able to weigh them up
- have adequate information on which to base their choices
- have no untoward pressure or coercion applied to them when making their choices.

Vulnerable people

Every recipient of health care is in some way vulnerable, but those with more limited ability to act autonomously can also be more vulnerable to the impact of research activity. For example, people whose first language is not English – such as deaf people who use sign language, some members of minority ethnic communities, or overseas visitors – can find it difficult to make reasoned decisions about their participation if they can't understand the issues or make their preferences known. Children and some specific groups of adults need special consideration.

Children

Autonomous ability develops with maturity, and children become gradually more autonomous as they grow older. Research shows that even very young children, of primary school age, can be capable of holding reasoned, well-informed views on issues that affect them.

There has been much work, in both legal and health care contexts, on the role of parents or guardians in assisting with, or being wholly responsible for, decisions about a child. In the *Children Act* 1989 (England) and the *Children Act* 1985 (Scotland), parental rights are linked closely to their responsibilities, and the laws make explicit the requirement for parents to act in their child's best interest. When children are unable to determine those best interests for themselves, then parents are normally the best alternative decision-makers.

So if you are undertaking research involving children, or working with them, you should support children's autonomy as much as possible, taking their views and preferences into account, while ensuring they are adequately protected if they cannot make their own decisions. We are all aware of the particular vulnerability of children in local authority care, and in these cases you will need to consider carefully the complexity of parental responsibility in each individual case.

Further information: Specific guidance on ethical conduct for including children in research is available from the Royal College of Paediatrics and Child Health. The Human Fertilisation and Embryology Authority addresses issues relating to research with embryos.

Vulnerable adults

Adults may also be vulnerable as research subjects or participants. Patients who are unconscious, have serious or enduring mental health problems, some older people and some individuals with learning disabilities may lack competence, either temporarily or permanently. But it is unwise and improper to dismiss too readily their intellectual ability. For example, most people who are termed 'older' retain full autonomous ability, and even those who demonstrate confusion are rarely confused about everything.

If you were researching mental health problems, you would need to consider the wishes of people who are unable to voice their own concerns. Some patients or clients may temporarily lack the ability to act autonomously, and may even be receiving treatment against their expressed wishes. The legal right and requirement to provide such treatment does not include the right to engage in research on the same individuals. The absence in law of any surrogate decision-maker for the individual in such cases makes acting without their expressed autonomous views problematic.

In all cases, you need to do your best to protect individuals' interests and autonomy. The law, too, recognises that autonomy is a complex issue which requires careful consideration of a variety of factors before you can arrive at a conclusion about the weight to be attached to an adult individual's decisions about health care. Many potential research subjects may be temporarily vulnerable: perhaps they have just received bad news about a poor prognosis, or they may be in the process of receiving important information about their health or care. In such situations, you will need to be careful not to cause information overload. Current developments encourage the involvement of users of services at as many levels of research as possible to reduce vulnerability where possible.

Further information: Useful information is available from INVOLVE (formerly NHS Consumers in Research). Guidance on involving people who are mentally incapacitated is available from the Medical Research Council. The American organisation National Alliance for the Mentally Ill offers guidance specifically on research with people with mental illness (its messages are relevant for

the UK). All research in Scotland involving adult subjects who are unable to consent for themselves is subject to the provision of the Adults with Incapacity (Scotland) Act 2000 and must be submitted for approval by the Multi-centre Research Ethics Committee (MREC) for Scotland (whether or not the study is multi-centred) – details on the COREC website.

Is research with vulnerable groups possible?

There is no doubt that undertaking research ethically with vulnerable populations is more difficult – but sometimes there is no viable alternative to including these groups. For example, drugs intended for use with children must be tested on children eventually – tests on adults alone cannot establish drug safety. Therapies to help people with debilitating mental illnesses can usefully only be tested on those affected by these illnesses (and, therefore, at least temporarily less autonomous than normal). To ban such research would further disadvantage many individuals who may be subject to institutionalised discrimination. Indeed, vulnerable and minority groups are often inappropriately 'invisible' in research. This places extra demands on researchers to involve, but also to protect those involved in studies.

Addressing the issues

There are three main areas you must cover to ensure research with human subjects is carried out ethically:

- ensuring consent
- protecting confidentiality
- balancing the risk of harm with potential benefit.

Consent

Patients who are able to consider what participation will involve have the right to decide whether or not to take part in a research study. You will need to make effective arrangements to:

- provide full information which is easy to understand
- ensure the individual's informed consent is given
- provide opportunities for participants to withdraw consent
- repeat consent procedures in longer studies to ensure consent is continued.

With more vulnerable groups of subjects, you may need to make extra efforts to achieve truly informed consent. Only in exceptional circumstances will the nature of a study and its likely benefits justify not gaining consent. The Department of Health website offers access to full text publications about consent, and the RCN has produced *Guidance for informed consent* (publication code 002 267).

Confidentiality

You must safeguard participants' dignity and privacy. This often means ensuring that personal information given as part of the study is kept confidential. In some cases research participants may need to be asked to maintain the confidentiality of information about other people that is revealed in meetings or focus groups.

Whatever the nature of the data, the researcher has an obligation to guarantee its secure storage, and make arrangements for disposal of materials on completion of the study. Data may exist in a wide variety of formats, and may include, for example:

- details of participants and their family
- extracts from medical records
- photographic, videotape, or electronic material

- human tissue.

Further information: As well as local guidance, you will find that the GMC has guidelines on the ethical use of videotape recording in research, including this vital issue of confidentiality. The Department of Health (England) offers guidance on the use of confidential patient information, and information on the Data Protection Act 1998 is provided by the Home Office. In the light of growing concerns about the ethical difficulties associated with the use of Internet-based research, the Association of Internet Researchers has appointed a working party for the development of ethical guidelines for online research.

Balancing risks and potential benefits

In an ideal world, no research would involve any risk or harm to anyone involved – but in health care, this is unrealistic. We have to accept that some of what we do as nurses may cause immediate harm, balanced by a more important long-term benefit (such as giving a painful injection of medication). Similarly, people who are research subjects may benefit directly from research interventions, but for many the benefits are less immediate, and they need to be made aware of the future benefits for others.

To gain approval from research ethics committees, a study should be reviewed in the light of both its short-term effects as well as its long-term goals. Committees are expected to adopt a practical approach and consider questions in three areas.

1. The goals of the proposed study.
2. The researcher's duties.
3. The rights of participants.

Study goals

If you are a prospective researcher, you should ask yourself:

1. how important is the research question that is posed?
2. can the proposed research answer the question?

Committees should allow only research that is expected to result in worthwhile findings – participants must not be inconvenienced or harmed to no justifiable end. It may be that a particular study, while well-designed, will ultimately serve no useful purpose. Alternatively, a study which sets out to answer an important

question, but which is poorly designed, is unlikely to provide answers in sufficiently rigorous terms.

Sometimes, small-scale research done as part of an education programme might not seem to meet these criteria. But in these cases, the benefit attaches to the development of research skills in novice researchers, balanced against the often minor inconvenience that such studies might create. Just like audits or research, the information collected in an educational case study could be harmful if misused, and it is important that research students follow institutional policy and are properly guided and monitored by a research supervisor.

The researcher's duties

The World Medical Association website has details of the international convention and agreements that identified the duties of a researcher. You can use these as sources of guidance. For the UK, the European Convention on Human Rights (now becoming part of national law) is also central, as is the Convention on the Rights of the Child.

The participant's rights

In order to ensure the protection and welfare of research subjects:

- the extent and precise nature of their participation ought to be clear before the study begins
- a risk-benefit analysis should be carried out.

You will need to identify risks to the physical or psychological health and welfare of subjects, and balance them against potential benefits – benefits that will often only manifest themselves in the future, and not directly for the participants. So ask yourself:

1. what will participating in the study involve? Is this made explicit?
2. are the risks necessary and acceptable? Are these made explicit?

Risks

All patient care and treatment contains an element of risk, as does all research – but the level of risk depends on the nature of the research. For example, the physical risks of anaesthesia, surgery or other invasive procedures, which might form part of a new treatment trial, are clearly greater than the potential risks of observing or interviewing patients or staff.

Even when safe for the majority of users, testing new procedures and treatments may cause harm, such as

allergic reaction, to particular individuals. Other risks are less obvious: for instance, interviewing people about sensitive subjects might provoke a reaction in some participants who will need further help. Data collected for one research project might sensibly be used for some other purpose, such as planning health care or another research project – but again, if there are risks that this could cause harm, such use should be restricted.

Whatever the nature of the investigation, potential participants should be able to make an informed decision about their participation based on knowledge of both the risks and potential benefits to themselves or others.

Potential benefits

The benefits of research can be many. For example:

- direct improvement in the health or care of individuals involved in the study
- more commonly, health care benefits for others in the longer term
- the improvement of care by nurses undertaking research as part of their professional development.

Some research will not prove to be of direct benefit, and may even prove harmful. It is not always possible to predict problems in advance, but studies should be designed in order to minimise any harm and with clear protocols to remedy any difficulties. This can be straightforward in clinical trials where the new treatment can be abandoned if it is found to be less beneficial, or even more harmful, than a rival treatment or no treatment at all. Decisions can be much more difficult in less structured, qualitative research approaches such as ethnography and action research.

Conclusion

Technological change, the drive for evidence-based practice and the need to evaluate health care delivery have created many opportunities for research, but also challenges to both experienced and new researchers. Whatever the quality and ethical control mechanisms available, as with care itself, much depends on the integrity and training of those involved – for those using research in practice, as well as those actually doing the research. As a practitioner, you have a responsibility to use research evidence if it is available, but you must use it wisely and after appropriate evaluation of its quality and relevance.

The NHS and other agencies have produced rules and frameworks to improve the approval and regulation of research. These can seem, at times, a bureaucratic and limiting factor for researchers, inclining them toward research designs which avoid many of the challenges. But with support from experienced researchers, you can negotiate these hurdles. The need for ethical approval should be no bar to any study that might improve the evidence base for nursing which patients, rightly, should expect to underlie their care.

Useful Internet resources

(Website addresses correct as of 12 January 2004.)

Professional bodies

The United Kingdom Nursing and Midwifery Council offers guidance for research and audit and a professional Code of Conduct not specifically focused on research at
www.nmc-uk.org/nmc/main/advice/researchandaudit.html

The UK Central Office for Research Ethics Committees (COREC) gives very comprehensive guidance to researchers and ethics committees, with criteria, application forms and procedures and a guide to many other useful sources
www.corec.org.uk

The Medical Research Council offers a number of publications in hard copy or as Adobe Acrobat PDF files (such as personal information in medical research, ethical management of human tissue in research, etc)
www.mrc.ac.uk/index/publications/publications-ethics_and_best_practice.htm

The RCN Research Society website carries further guidance
www.man.ac.uk/rcn/

The General Medical Council provides advice to doctors on good practice in research, and this advice can be useful to other professions, too
www.gmc-uk.org/standards/research.htm (General guide)

www.gmc-uk.org/standards/aud_vid.htm (Specific to the use of video and audio recording in research)

A Code of conduct is provided by the British Psychological Society
www.bps.org.uk/index.cfm

The Market Research Society provides a code of conduct together with best practice guides
www.marketresearch.org.uk/

The Association of Internet Researchers has a working party to develop guidelines for researchers
www.aoir.org

UK National/International guidance

England

The Department of Health offers its own guidance on the expanded topic of 'research governance' which includes financial, intellectual property, and other issues
www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/fs/en

All relevant current regulations relating to Research Ethics Committee policy can also be found at this address.

Northern Ireland

Department of Health and Social Services Northern Ireland
www.dhsspsni.gov.uk

Research Governance Framework for Northern Ireland
www.dhsspsni.gov.uk/publications/2002/researchframework.pdf

Wales

National Assembly for Wales
www.wales.gov.uk

Research Governance Framework for Wales
www.word.wales.gov.uk/content/governance/governance-e.htm

Scotland

Scottish Executive Health Department
www.scotland.gov.uk

Research Governance Framework for Scotland
www.show.scot.nhs.uk/cso/

Consent

The full text of publications relating to consent may be found at the Department of Health
www.doh.gov.uk/consent/

Additional guidance is provided by the General Medical Council
www.gmc-uk.org/standards/default.htm

Vulnerable Groups

Guidance specifically on ethical conduct for including children in research is available from the Royal College of Paediatrics and Child Health
www.rcpch.ac.uk

Guidance on the Ethical Conduct of Research on the Mentally Incapacitated is available form the Medical Research Council
www.mrc.ac.uk/index/publications/publications-ethics_and_best_practice/publications-ethics_series.htm

The National Alliance for the Mentally Ill (an American consumer organisation) offers wide-ranging

information about the participation of people with mental health problems in research
www.nami.org/Content/NavigationMenu/Inform_Yourself/About_Research/About_Research.htm

Issues relating to research with embryos are addressed by the Human Fertilisation and Embryology Authority
www.hfea.gov.uk/Research

INVOLVE (Formerly NHS Consumers in Research)
www.invo.org.uk/

Law and Conventions

For worldwide agreements on research ethics, the World Medical Assembly holds details
www.wma.net

The Human Rights Act 1998
www.hmso.gov.uk/acts/acts1998/19980042.htm

Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being

http://conventions.coe.int/

Details and text of the convention on the Rights of the Child can be found at
www.unicef.org/crc/crc.htm

Details of the Data Protection Act 1998
www.dca.gov.uk/foi/datprot.htm

Law in Scotland relating to adults with incapacity
www.scotland-legislation.hmso.gov.uk/legislation/scotland/

Assistance in navigating through the Act is to be found at:
www.scotland.gov.uk/about/JD/CL/00016360/home.aspx

The Race Relations Act 1976 & Race Relations (Amendment) Act 2000
www.hmso.gov.uk/

and explanatory guidance from the Commission for Racial Equality at
www.cre.gov.uk

Each of these sites offer access to publications relevant to the countries of the UK

Some studies will impact on health and safety at work or involve hazardous substances. Advice on regulations may be found at the Health and Safety Executive:
www.hse.gov.uk

Additional references to printed resources are provided by the Royal College of Nursing website
www.rcn.org.uk/learning/learning_library_information.html

In addition, many RCN publications contain information on consent in specific contexts, for example:

Working in independent and boarding schools. Guidance for nursing staff (2003), publication code 002 168

Digital rectal examination. Guidance for nursing staff working with children and young people (2003) publication code 002 062

You can download copies of RCN publications from the members' area of the RCN website
www.rcn.org.uk/members/publications/

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