Research ethics

RCN guidance for nurses
This publication is a revised edition of *Research ethics, RCN guidance for nurses* first published in 2004.

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Published by the Royal College of Nursing, 20 Cavendish Square, London, W1G 0RN

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Research ethics

*RCN guidance for nurses*

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Introduction

There has been growing recognition in recent decades of the need for health service provision to be based on the best available evidence, rather than on custom and tradition (Stevens et al., 2001). It has also been acknowledged that achieving this requires the sustained efforts of researchers, practitioners, educationalists, managers, politicians and the public to generate this evidence through the commissioning and conduct of high quality research.

The potential for nurses to be involved in research has grown exponentially since the Royal College of Nursing (RCN) published its first guidance on research ethics for nurses in 1977. As a result, nurses may be involved in carrying out their own projects, collecting data for other lead investigators, reviewing research protocols, commissioning research or acting as participants in research. In all of these roles, it is important that the nurse possesses an understanding of the important issues in research ethics that should underpin research practices.

This guidance seeks to build on the 2004 edition, by providing the reader with an overview of recent developments in research ethics, while indicating where further information can be gained. For example, a ‘principles’ approach to biomedical research ethics will not be provided here, but is explored elsewhere (Beauchamp & Childress, 2001). The booklet is divided into short sections, accompanied by relevant references and internet sources, which readers are encouraged to access. Nurses may undertake research in a range of settings including NHS, private sector, overseas, local authorities and the voluntary sector. Although there are many different types of research – such as service evaluations, clinical trials or action research studies – the ethical principles that should guide those involved remain constant. It is hoped that this text will provide an introduction to these, signposting the reader to further resources as needed.

Readers should be aware that guidance relating to the management of research and the structure and function of organisations – such as ethics committees – and the implementation of research governance requirements, is fluid and may well change in response to the needs of the NHS.

The role of the nurse in research

The contribution of research to nursing knowledge and competence continues to influence patient care standards. Undoubtedly, there is a continuing need for good research evidence to fuel and support contemporary nursing practice. Accordingly, and similar to other professional groups in the health services, many nurses are now responsible for initiating new and innovative therapies through research in a variety of ways.

Whatever research role is adopted, there is a need to make sure that research is of good quality. All nurses have a duty of care to their patients, each of whom is entitled to safe, competent care (Nursing and Midwifery Council, 2007). This also extends to their involvement in research and, in common with other professionals nurses are obliged to ensure that research is safe, robust and ethical. The Nursing and Midwifery Council (NMC) offers some guidance for practitioners interested in research and audit, the A-Z fact sheet contains criteria for safe and ethical conduct of research and is a useful guide for novice researchers. The RCN also provides guidance on informed consent in health and social care research.

Useful resources

For further information from the NMC refer to: www.nmc-uk.org.

For further details from the RCN about informed consent visit: www.rcn.org.uk/development/publications/publications A-Z.
Student research

Many nurses and other health care professionals undertake small research projects as part of their post-qualifying education. If student research involves NHS patients, service users, relatives or carers, staff or NHS premises, it must be reviewed according to the requirements of governance arrangements for research ethics committees. It will also require review by a local research ethics committee (LREC) and the appropriate university ethics committee. Guidelines for the completion of LREC forms for student projects have been produced by the Association of Research Ethics Committees (AREC, 2002).

When completing the LREC form, many students get confused by jargon that surrounds the concepts of ‘sponsorship’. In this instance, sponsorship does not refer to the financing of the project. Rather, the sponsor is a representative of the researcher’s employing organisation, or the university at which the student is studying. The sponsor’s role is to guarantee the quality of the research environment and the competence of the research team. For students employed by the NHS, it is often better to identify their employing trust as the sponsor, since this can be negotiated as part of the governance application. Responsibility for the safe, robust conduct of the research in question lies with the principal investigator. However the investigator’s employing institution is also responsible for ensuring that the appropriate quality monitoring mechanisms are in place.

Research in developing countries

Increasing opportunities are arising for nurses to undertake research in developing countries. Whilst some of these countries are developing research policies and procedures, this is a relatively infrequent activity which tends to focus on the conduct of drug trials. Prior to commencing any study it is essential that steps are taken to prevent any research misconduct, poor performance or exploitation of subjects. This is particularly the case when undertaking research with participants who may be considered vulnerable.

Nurses wishing to undertake studies in developing countries are advised to contact the host institution to locate the existence of any guidelines. These can then be followed in conjunction with standard university and NHS ethics and governance guidelines concerning recruitment, consent, data collection and so on.

Key information

More specific guidance that includes payment of volunteers and obtaining consent as well as a wealth of practical points is available on the Nuffield Council on Bioethics web site available from: www.nuffieldbioethics.org.

Key information

National Research Ethics Service
www.nres.npsa.nhs.uk.
Informed consent

Informed consent is central to ethical practice. Usually, it should be obtained before entering or recruiting any subject or participant into a research project. Those who enter research should be fully informed of the research aims and potential benefits and harms, giving their consent voluntarily. At no time should the individual feel coerced to participate in a study, or be unduly persuaded by the promise of a reward. Research participants need to be aware of any risks that may occur as a result of their involvement in the research.

Informed consent requires that this information is transparent and in a language which the participant can understand. Information should be verbal and written, and time should be provided for the participant to consider their involvement in the study and to ask questions. Ideally, a consent form should be signed and witnessed. However, in some instances this is not always practical or a requirement. For example, a researcher undertaking a non-intervention study, relying on non-participant observation of the provision of services or care, would be unable to obtain the consent of every individual who passed in view.

Formally recruited research participants have the right to withdraw from a research study, without prejudice and without impact on their care. This should be made explicit to the participant at the start of the research – usually when informed consent is obtained. Where there is doubt over an individual’s ability to provide an informed consent, due to lack of understanding, methods of addressing this should be detailed in the study protocol. Nurses working as part of a clinical team should not have to take responsibility for recruiting and seeking the consent of study participants, unless they are sufficiently informed about the study and feel able to do so. Whilst it is often the delegated role of some nurses, for example, clinical trials nurses, to take informed consent, they must be adequately trained for this and the delegation must be documented.

Furthermore nurses may act as advocates and assist participants to obtain the information they need when they do not have the necessary information or do not appear to understand aspects of the study proposed by other professionals.
The Mental Capacity Act for England and Wales 2005 has implications for researchers with particular regards to participation and consent to involvement. Key elements relate to capacity to consent, support for people to make decisions, unwise decisions, best interests and least restrictive options.

### Key information

For further details and a standard format consent form, visit the National Research Ethics Service (NRES) at: www.nres.npsa.nhs.uk.

For information from the Department of Health about consent visit: www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Consent/index.htm.


### Confidentiality and data protection

Usually, it is wise for the confidentiality and anonymity of research participants to be preserved by coding data or assigning individual participants with pseudonyms. For example, the identity of research participants should not be recognisable in research reports detailing study findings or in any presentation of findings. There may be exceptions to this in some types of research – such as action research – where participants may view themselves as co-researchers and may wish their contributions to be recognised. However, the Data Protection Act (DH, 1998) emphasises that researchers are responsible for ensuring compliance with the Act, in relation to data storage and the way in which access to data is managed.

All confidential data should be stored in a locked cabinet, with authorised access. Although there are good scientific arguments for much longer storage of raw data – such as the prevention of academic fraud (Long & Johnson, 2007) – in health and social care contexts, data is usually stored for up to five years. Some individual organisations may have their own requirements and it is wise to check. For example, some ethics committees recommend up to 30 years, depending on the nature of the data. Research participants need to be fully aware of these details and reassured that any data pertaining to them is safe.

Applications from researchers to access confidential patient information for research purposes can now be made to the National Information Governance Board for Health and Social Care through its Ethics and Confidentiality Committee. Available from www.nigb.nhs.uk/ecc.

Caldicott guardians are usually senior staff who work in the NHS and social services who are appointed to protect patient information. Ideally, Caldicott guardians should work with ethical and research governance structures to ensure that the Data Protection Act 1998 is followed.

### Useful resources


Also see the NRES website at: www.nres.npsa.nhs.uk.
Research involving people who are vulnerable

The phrase ‘people who are vulnerable’ may encompass a multitude of different populations – for example, children, people with mental illness or learning disability, people with communication difficulties, prisoners or young offenders. In varying degrees, other groups could also be considered to be vulnerable, such as people who are deaf or sight-impaired, or those individuals for whom English is not readily understood. In theory, any person who is receiving health care could be considered to be vulnerable. However, vulnerability should not be considered a label, applied as a blanket term to specific groups.

In relation to research, the term implies that the individual may not be able to understand what their participation in a research study will involve, or who finds it difficult to make their wishes and preferences known. The result is that the individual may be less able to make an informed or reasoned decision about their participation. To this end, there is potential for the individual to be either manipulated or misled, or to make a decision that they may regret.

It is important that all potential research participants have sufficient time to consider whether they wish to take part in a research study. This may be particularly important when including people with learning disabilities in research (Cameron & Murphy, 2006). Ensuring this happens requires planning on the part of the researcher.

When involving individuals who may be considered to be vulnerable, extra care must be taken in the provision of information about the research, and promoting the individual’s autonomy when seeking consent. A range of guidance exists – for example, see Lewis & Porter (2004).

Some organisations have developed ‘vulnerable adult policies’, while research ethics committees may request that researchers apply a test of competency to potential research participants. Where the adult individual cannot provide informed consent, it is common to request the consent of the next of kin.

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. Research projects must be submitted to the Multi-Centre Research Ethics Committee (MREC) for Scotland, even if the study is not multi-centred. In mental health, although at times some patients may be receiving treatment against their wishes, this does not mean that the individual must also participate in research against their wishes.

Research involving children should seek the child’s and/or the parent’s consent, where appropriate – see the Children Act 1989 for England and 1985 for Scotland. In general, a more demanding rule is set for consent when involving children in research, compared to consent relating to medical treatment. In research studies when an adult makes decisions for a child who is too young to decide for themselves, as well as ensuring the consent of the parent or guardian, the researcher should, at least, also make sure that the child does not object to participation.

If participating in non-therapeutic research, the Medical Research Council (2004) allows for only a negligible risk of harm to children. In therapeutic research with children, it demands that possible risks must be outweighed by likely benefits. In clinical trials, parental consent is always required (EU Directive 2001/20/ED).

There is a need to limit guarantees of confidentiality to children taking part in a research study. Researchers have a clear responsibility to divulge information if there is the potential that a child may be harmed. However, before doing so they must discuss this with the child.

Although involving vulnerable populations in research can be complex, time-consuming and ethically challenging, it remains an important necessity. In the longer term, if vulnerable groups remain ‘invisible’ in research they will be further disadvantaged, as their views, experiences and needs will not be represented within the evidence base.

Others who may be less visible and so marginalised and seldom heard are transient populations such as people seeking asylum, travellers and people who are housebound. Also overlooked are those who it may be difficult to identify in advance such as homeless people attending a drop-in centre. In such instances research is required that is both responsive and responsible and efforts should be made for their inclusion wherever appropriate. The Scottish Executive (2002) provides guidance on targeting so-called ‘hard to reach’ groups through a number of strategies such as ‘grass roots’
Increasingly, it is seen as ethically appropriate that active partnership will be promoted between the public and researchers in the research process, rather than people being viewed as 'subjects' of research. Involvement is commonly described as research carried out 'with' or 'by' the public, rather than 'to', 'about' or 'for' the public. Where possible, it is advocated that service users should be involved in all stages of the research process. This includes the development of ideas and prioritisation; design of studies; methods of data collection; dissemination of findings; and overall study management.

How patients and the public choose to be involved should be discussed and agreed with them. It is desirable to recognise and reward service users for giving up their time and to recompense travel expenses, in addition to meeting any support and training needs which may arise. Participants should always be advised to seek advice on how any payments may affect their personal circumstances, for example, from their benefits office.

At the beginning of a study, it is not always possible to know what opportunities there may be for public involvement. Opportunities may occur for deeper engagement in a project, or withdrawal by the person in a particular role. As a result, an individual's involvement may vary over the lifetime of a study. It is perceived by some that service users have the right to be involved in research that concerns them. There is an emerging consensus that involvement has a positive impact on the quality of research.

Guidance relating to involving people with mental illness in research is available at: www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002409.

Guidance relating to involving children in research is available at: http://adc.bmj.com/cgi/content/full/82/2/177.

Robust, quality research designs

Good research rests on a good research design. All those involved in research must ensure that appropriate research methods have been selected to answer given research questions. In addition, the research protocol should be peer-reviewed and approved by relevant ethics committees. It is advised that this process is not undertaken in isolation.

To provide support for researchers, local peer review networks have been developed in many areas to help ensure that proposed research is of good quality.

Researchers should locate their local peer review system to help develop and refine the research protocol. Further support is also provided by the national network of research and development support units for health care research. In England, these units are funded by the National Co-ordinating Centre for Research Capacity Development. They aim to support high quality and multidisciplinary health and social care research. They provide a range of courses and training programmes to assist the development of capability and capacity, helping to increase research awareness through local and national meetings.

For nurses working in the clinical setting who may be asked to facilitate a research study or collect research data, it is important to recognise the limits of this role. For example, if a research participant requests an in-depth explanation of a study and its design, nurses with any doubts about their ability to answer the questions should refer the individual to the research’s lead investigator.

Useful resources

For further information about the National Coordinating Centre for Research Capacity Development contact: www.national-rdsu.org.uk.

Gaining research governance approval for your study

Since 2001, the UK Government health departments have implemented the Research Governance Framework to strengthen public confidence in research and improve the management and monitoring of research. The framework relates to set standards that outline the key principles of a quality research culture in five governance domains. Additional legislation, published in April 2001, resulted in European directives to support the development of robust research (91/507/EEC). This guidance – used in conjunction with research governance – provides the public with added assurances of safety and quality, helping to foster a quality research culture across all organisations.

The Research Governance Framework is of relevance to those who host, carry out or participate in research. All nurses involved in research, at whatever level, should be familiar with the framework, and ensure that research adheres to its key principles. The research governance standards relate to five domains: ethics; science; information; health, safety and employment; finance and intellectual property.

The ethics domain is concerned with ensuring that the dignity, rights, safety and well-being of participants are the primary consideration in any research study. In addition, data protection, ethics committees, informed consent and confidentiality are integral concerns to the research process. The science domain argues that unnecessary research duplication is unethical and that only original high quality research should be generated. In practice, this means that existing sources of evidence should be used and all research proposals should be subject to peer review. Special guidance is given for research involving human embryos, animals, genetically modified organisms, and medicines. The information domain highlights the need for information on research and subsequent findings to be accessible to the public through publication.

To ensure that research findings are visible, NHS trusts previously had a responsibility to enter ongoing and
completed research projects into the web-based National Research Register. This facility is no longer active however archived study information remains available from https://portal.nihr.ac.uk/Pages/NRRArchive.aspx.

Until December 2007, the National Research Register provided information on research taking place in NHS organisations in England, Scotland and Wales. The development of Clinical Research Networks has shifted the responsibility for registering eligible research from NHS organisations to the researcher and the topic network. Data is no longer submitted or collected from NHS organisations. Further information can be found at the NIHR portal: https://portal.nihr.ac.uk/Pages/NIHRResearchInfoStatement.aspx.

The health, safety and employment domain recommends that the safety of research participants and staff is assured by adhering to health and safety regulations. New or existing medical devices need to be approved by the Medical Devices Agency to ensure safety for staff and patients. Finally, the finance and intellectual property domain advocates compliance with the law and rules set for the use of public funds. Compensation is recommended for anyone harmed as a result of studies. Intellectual property (IP) is concerned with inventions, know-how (knowledge), copyrights and database rights, designs, trademarks and materials. For example, it should be agreed who will be credited with funds and authorship at a study's outset.

To find out about the research governance arrangements in a specific NHS trust or organisation, contact their research manager.

Key information

Visit the Department of Health's website: www.dh.gov.uk.

For the UKCRC, visit www.ukcrc-rgadvice.org.

Archived NRR information remains available from https://portal.nihr.ac.uk/Pages/NRRArchive.aspx.

Gaining ethical approval for your study

In the UK, research ethics committees (RECs) are formed of voluntary members, of which one-third are lay – that is, non-health care related. The rest of the committee members provide medical, educational and scientific experience and expertise. Each committee is supported by a local administrator and by the National Research Ethics Service (NRES) Providing it is not a clinical trial of a new medicinal product, a study that is to be held on one site can be considered by the local research ethics committee (LREC). If the study is to be held on many sites that fall within one domain – in other words, an area that is the remit of one specific body or organisation – then the applicant can be reviewed by any LREC in that area. If the study is being conducted on multiple sites spanning two different domains, the applicant may submit to both LRECs covering those geographic areas. If the project spans more than two separate geographical areas, the applicant should submit to one of the flagged committees that deal specifically with research relating to HTA, such as that involving human tissue banks, genetics or vulnerable groups, for example research with prisoners. The REC co-ordinators will be able to advise you further. A list of REC co-ordinators can be found on the NRES website (www.nres.npsa.nhs.uk). Although the NRES form can look daunting, taking a systematic approach to completing the sections helps to make it more manageable. LRECs have to respond within 60 days to applications. However, it is worth building several months into research plans or proposals to allow enough time to gain ethical and research governance approval. For example, researchers may need to complete an enhanced Criminal Records Bureau check or undergo occupational health screening. To supplement the practical information on NRES website, Haigh (2007) has produced guidance on the elements of successful ethical review. This provides useful tips for both novice and experienced applicants.

Key information

Also visit the Medical Research Council: www.mrc.ac.uk/Newspublications/Publications/Ethicsandguidance/index.htm.

Research governance in the global arena

The global drive to ensure high quality research is evident in a range of countries where similar ethical and governance frameworks have been developed. These promote robust, ethical and safe research in order to prevent research misconduct and poor performance (Howarth & Kneafsey, 2007). It has also become more common for research studies to take place in multiple sites spanning several countries. Often these large-scale studies have been designed to assess the efficacy of new drugs and therapies, or to gather epidemiological data. As such, they require large sample sizes.

For nurses directly involved in this kind of research, the need to adhere to ethical research principles remains paramount. Within Europe, there are also a number of directives that focus on research ethics in specific areas, for example, clinical trials. Nurses involved in such research should check the European Union website on a regular basis for new developments or guidance.

Key information


Human Tissue Act

In the current UK research climate, it is highly unusual for nurses to be the principal investigator leading research that involves the collection and storage of human tissue. Nonetheless nurses are involved in such research as clinical research nurses. They may be part of larger, often physician-led, teams and are regularly concerned with issues such as obtaining consent from study participants. Therefore it is important that nurses in these situations are aware of the responsibilities they carry under the Human Tissue Act (HTA) 2004.

Fundamentally, the HTA covers all ‘re relevant material’ – which is defined as any material containing human cells, except gametes and fetal material outside a woman’s body. This includes hair and nails from living people. The primary principle of the Act is one of explicit and appropriate consent. The Act itself is extremely complex, but Brazier and Forvargue (2006) have produced an excellent, brief guide exploring its ramifications in more detail.

Key information

Conclusion

The generation of research evidence is crucial to the provision of safe and effective health and social care. If research is based on a robust design and is conducted in a safe and ethical manner, the process and outcome of knowledge generation can be of benefit to everyone involved.

As this guidance illustrates, a range of resources can be readily accessed to support nurses undertaking a research study. However, guidance published by the NMC, RCN and DH is subject to change. It is worth remembering to identify any changes before you embark on your study. As you develop your research project, you will come into contact with many of the organisations listed here, through which you will be able to keep abreast of fluctuations in ethical or governance requirements.

Most importantly though, many of the key concepts outlined in this guidance – such as the safety of participants – will remain constant, no matter what type of research you undertake. You should be mindful of these elements, remembering that at the heart of all robust and ethical research is respect for individuals and protection of those who may be vulnerable.

Key information

For the Association of Internet Researchers, please refer to www.aoir.org.

Internet ethics

The development of the internet over recent years has seen a corresponding growth in the development and use of internet-based research methods. There are numerous approaches that lend themselves to internet research, including: web page content analysis; online focus groups; online interviews; and analysis of e-conversations.

Many of the concerns surrounding the ethics of online research are identical to those of ‘real world’ research. The Association of Internet Researchers (AoIR) argues that certain issues require greater consideration than is generally expected from real world human subject research. It has highlighted the potential difficulties in maintaining participants’ privacy and confidentiality; gaining informed consent; and ascertaining the identity of subjects in the world of online research. However, the AoIR Internet ethics report (2002) stopped short of providing a specific internet ethics framework. Instead, it places the burden of ethical decision-making inherent in internet research firmly back with the researchers themselves.

Haigh and Jones (2005) have provided an analysis of the ethical dilemmas that underpin cyberspace research. Any person planning on undertaking such research should be aware that extra ethical consideration might be required, when using cyberspace as a research environment.
References


Cameron L and Murphy J (2007) Obtaining consent to participate in research: the issues involved in including people with a range of learning and communication disabilities, British Journal of Learning Disabilities, 35 (2), pp. 113-120.


Other web-based resources

(Websites correct as of 9 February 2009)

The General Medical Council provides guidance on good practice in research for doctors that may also be valuable to others: www.gmc-uk.org/guidance/a_z_guidance/index.asp.

The British Psychological Society has published a code of ethics and conduct in research: www.bps.org.uk/thesociety/code-of-conduct/code-of-conduct_home.cfm


www.humantissueauthority.gov.uk.

Other UK national guidance

In England, the Department of Health for England provides guidance about research governance and other research related issues: www.dh.gov.uk/Home/fs/en.

In Northern Ireland, visit the Department of Health and Social Services for Northern Ireland at: www.dhsspsni.gov.uk.

In Wales, visit the National Assembly for Wales at: www.wales.gov.uk.


In Scotland, visit the Scottish Executive Health Department at: www.scotland.gov.uk/home.

Law and conventions


For worldwide agreements on research ethics, the World Medical Assembly holds details. See: www.wma.net/e/policy/b3.htm.


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

Law in Scotland relating to adults with incapacity can be located at: www.opsi.gov.uk/legislation/scotland/acts2000/2000004.1.htm.


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

The World Medical Association has published a new version of the Declaration of Helsinki. The 2008 version is now the only official one; all previous versions have been replaced and should not be used or cited except for historical purposes. Website: www.wma.net/e/policy/b3.htm.
The RCN represents nurses and nursing, promotes excellence in practice and shapes health policies

**March 2009** third edition
**Review date January 2011**

RCN Online
www.rcn.org.uk

RCN Direct
www.rcn.org.uk/direct
0845 772 6100

Published by the Royal College of Nursing
20 Cavendish Square
London
W1G 0RN

020 7409 3333

Publication code 003 138

ISBN 978-1-906633-08-0